UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

[UNDER SEAL],

Plaintiff,

v.

[UNDER SEAL],

Defendants.

Civil Action No.: 20-CV-3207 (MKV)

FIRST AMENDED COMPLAINT

FILED UNDER SEAL
PURSUANT TO
31 U.S.C. § 3730(b)(2)

DEMAND FOR JURY TRIAL

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, VIRGINIA, WASHINGTON, PUERTO RICO *ex rel.* JANE DOE,

Plaintiffs,

v.

HORIZON THERAPEUTICS, PLC., HORIZON THERAPEUTICS, INC., HORIZON THERAPEUTICS USA, INC., HORIZON THERAPEUTICS LLC, JOHN BOTSON, MD, ORTHOPEDIC PHYSICIANS ANCHORAGE D/B/A ORTHOPEDIC PHYSICIANS ALASKA, JEFF PETERSON, MD, WESTERN WASHINGTON MEDICAL GROUP, INC., P.S., AND JOHN AND JANE DOES,

Defendants.

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RELATOR JANE DOE'S FIRST AMENDED COMPLAINT

On behalf of the United States of America, Plaintiff-Relator Jane Doe, ("Relator"), by and through the undersigned counsel, files this *qui tam* Complaint against Defendants Horizon Therapeutics Public Limited Company and its subsidiaries operating in the United States ("Horizon"), Dr. John Botson, MD ("Dr. Botson") and Orthopedic Physicians Anchorage d/b/a Orthopedic Physicians Alaska ("OPA"), and Dr. Jeff Peterson, MD ("Dr. Peterson") and Western Washington Medical Group, Inc., P.S. ("WWM") (collectively, "Defendants") alleging as follows:

I. INTRODUCTION

1. In 2010, the FDA approved KRYSTEXXA® (pegloticase) ("Krystexxa") – administered intravenously every two weeks – for the treatment of chronic gout, a severe form of inflammatory arthritis caused by the accumulation of uric acid, in patients refractory to conventional therapy. Historically, Krystexxa did not sell well due to concerns about safety risks outweighing its benefits, and because of the costs, infrastructure and risks from the need for administration by infusion. The high cost of the drug itself was also a concern, with a small market of patients who are both insured and treated by doctors willing to offer on-site intravenous infusions of the drug. In 2011, during its first year on the market following FDA-approval, Krystexxa generated approximately $3.1 million in sales. Savient Pharmaceuticals, the company which first commercialized the drug, could not find a sufficient market for Krystexxa, and went bankrupt three years after launching the drug. Crealta Holdings LLC acquired the rights to Krystexxa at that time.

2. In 2016, Horizon acquired the rights to manufacture and sell Krystexxa when it completed its acquisition of Crealta Holdings LLC. After the acquisition, Horizon raised the

price of Krystexxa dramatically and began an illegal marketing campaign to expand the sales of Krystexxa. After the FDA refused to approve changes to the drug's warning label, Horizon misbranded and marketed the drug off-label by falsely misrepresenting the serious risks posed by the drug, including infusion reactions and anaphylaxis, and by paying kickbacks to physicians who were the leading prescribers of the drug.

3. Horizon's schemes involved manipulating clinical trial data to support fraudulent claims of Krystexxa's safety and efficacy; fraudulently downplaying and misrepresenting the specific and known health risks of Krystexxa; ghostwriting a "scientific" medical article published in a medical journal to give the false impression that promotional literature for Krystexxa was backed by independent science and research; the use of misleading promotional material that misrepresented the efficacy and health risks of Krystexxa and cited to the ghostwritten "scientific" medical article; the use of sham "safety board" meetings with physicians to mislead them about the safety profile of the drug, and feed them false information that contradicted and undercut the FDA-approved label and warnings; and finally, paying hundreds of thousands of dollars in kickbacks to the two doctors who were the biggest prescribers of Krystexxa to reward them for past prescription sales, incentivize them to maintain or increase their volume of prescriptions, and bolster their research credentials to make them appear more credible when speaking on behalf of Horizon to increase sales of Krystexxa.

4. Horizon's campaign to sell Krystexxa through misbranding and off-label promotion constitutes a fraud upon Medicare, Medicaid, Tricare and other government health programs, which have paid significant funds for Krystexxa for their members. According to reports to its investors, Horizon has managed to double and even quadruple annual sales of Krystexxa to over $250 million and is currently targeting $1 billion in projected annual sales – a

remarkable goal given that Savient Pharmaceuticals had only $3.1 million in sales less than 10 years ago in Krystexxa's first year on the market and Horizon only acquired the drug four (4) years ago.

5. After the FDA refused to allow Horizon to modify the black-box warning on the Krystexxa label, kickbacks to doctors have played a central role in disseminating Horizon's off-label messages and swiftly growing prescriptions. Horizon's false and misleading claims about Krystexxa have already led to misconceptions by physicians and patients about the safety profile of the drug. These misconceptions have increased sales by millions annually. As a result of this nationwide scheme, Horizon has violated and continues to violate the False Claims Acts and reap profits far beyond those it could achieve from legitimate promotion, in addition to putting patient safety at risk.

6. This is an action to recover treble damages and civil penalties on behalf of the United States of America (the "Government") from Defendants for knowingly and/or recklessly presenting or causing to be presented false claims to the Government in violation of the federal False Claims Act, 31 U.S.C. §§ 3729, *et seq.* ("FCA") and applicable regulatory guidance in order to illegally increase the sales of Krystexxa. The illegal acts alleged herein were personally witnessed by Relator when they worked at Horizon.

7. Defendants have committed various types of fraud against Medicare, Medicaid, and other government payors (collectively, "Government Programs") and private insurers. These types of fraud include off-label promotion of a prescription medication to downplay risks and boost sales, after the FDA refused to allow Horizon to modify the drug's warnings, and submitting claims tainted by kickback violations. These illegal acts began at least as early as 2016, and continue through the present (the "Covered Period").

8. As a result of these improper practices, numerous false claims were submitted to Government Programs during the Covered Period. Defendants' schemes caused Government Programs and private insurers to pay reimbursements for Krystexxa that would not have been paid but for Defendants' illegal conduct, which is specifically prohibited by federal and state law, regulations, and policies.

9. Defendants have actual knowledge that they are engaging in illegal conduct, including knowledge that the off-label promotion that falsely and unsafely downplayed the risks of the medication to drive prescriptions; such prescriptions are not entitled to payment and such improperly obtained payments must be refunded to the Government, particularly, because concerns were raised by and among various employees of Horizon such as the Relator and the regulatory staff assigned to review promotional materials, but any concerns were overruled by senior Horizon leadership, and Horizon continued its scheme to defraud the Government Programs and private insurers. Defendants have chosen to profit from fraudulently billing Government Programs and private insurers instead of disclosing the true nature and extent of the risks of Krystexxa or the kickbacks paid to drive sales.

II. PARTIES

A. Relator's Background

10. Plaintiff-Relator Jane Doe is a citizen of the United States. Relator personally witnessed and gained direct and independent knowledge of the information on which the below allegations are based, and Relator has voluntarily disclosed such information to the Government pursuant to 31 U.S.C. §3730(e)(4)(B)(i). To the extent any of Relator's allegations have been publicly disclosed as contemplated by 31 U.S.C. §3730(e)(4)(A), Relator is an original source and Relator's knowledge is independent of and materially adds to those allegations pursuant to 31 U.S.C. §3730(e)(4)(B)(ii).

B. Background on Defendants

11. Defendant Horizon Therapeutics PLC is a listed, public limited company, organized in Ireland and founded in 2008 (a public company since 2011). Its principal place of business is Connaught House, 1st Floor, Burlington Road, Dublin 4, D04 C5Y6, Ireland. Horizon operates through a number of international and U.S. subsidiaries as a pharmaceutical company; it conducts extensive business in the United States through a number of subsidiaries organized in the State of Delaware, namely, Horizon Medicines LLC; Horizon Ophthalmology, Inc.; Horizon Orphan Holdings LLC; Horizon Orphan LLC; Horizon Pharma Rheumatology LLC; Horizon Therapeutics, LLC; Horizon Therapeutics Services LLC; Horizon Therapeutics USA, Inc.; Horizon Therapeutics, Inc.; and HZNP USA LLC (collectively, "Horizon").

12. Horizon develops, acquires, and commercializes late-stage biopharmaceutical therapies for the treatment of pain and inflammation as well as specialty and orphan diseases. Its global headquarters are located in Dublin, Ireland and its U.S. operations are headquartered in Lake Forest, Illinois (a suburb of Chicago). The company employs over 1300 people with facilities in, among other locations, Illinois (Lake Forest and Chicago), Washington, DC, Ireland (Dublin) and Germany (Mannheim). In the U.S., in 2018 Horizon boasted a sales force of approximately 420 sales representatives consisting of approximately 25 orphan disease sales representatives, 140 rheumatology sales specialists and 255 primary care sales representatives.[1] As of December 31, 2019, Horizon now has 480 sales representatives and 170 rheumatology

[1] *See* 2018 Horizon Form 10-K, filed with the U.S. Securities and Exchange Commission, for the fiscal year ended December 31, 2018 ("2018 Horizon Form 10-K") at 13.

sales specialists.[2] Horizon recently announced an expansion of U.S. activities with the purchase of a 70-acre campus in Deerfield, Illinois.[3]

13. Horizon manufactures Krystexxa and other "orphan drugs" – these are medicines intended to treat a rare disease or condition affecting fewer than 200,000 individuals in the United States, or less than 0.0006% of the population. In addition to Krystexxa, Horizon's medicine portfolio includes: Ravicti (for urea cycle disorders), Procysbi (for nephropathic cystinosis), Actimmune (for chronic granulomatous disease and severe, malignant osteopetrosis), Rayos (for rheumatoid arthritis, polymyalgia rheumatic, systemic lupus erythematosus and multiple other indications), Buphenyl (for urea cycle disorders), and Quinsair (for treatment of chronic pulmonary infections due to *Pseudomonas aeruginosa* in cystic fibrosis patients). Horizon also produces primary care medicines: Pennsaid (for pain of osteoarthritis of the knee), Duexis (for signs and symptoms of osteoarthritis and rheumatoid arthritis), Vimovo (for signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis) and Migergot (therapy to abort or prevent vascular headaches, such as migraines). In 2020, the FDA preliminarily approved Horizon's Teprotumumab (for treatment of thyroid eye disease).

14. Horizon had $1.2 billion in total company net sales in 2018, including $355 million in the Fourth Quarter of 2018 when net sales increased by 30%. In 2019 Horizon had $1.3 billion in total company net sales, with net sales of Krystexxa totaling approximately $370 million. Shares have traded as high as $38.56 per share in the past six months. Horizon currently projects annual U.S. sales of $1 billion for Krystexxa alone. U.S. and foreign licenses

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[2] *See* 2019 Horizon Form 10-K, filed with the U.S. Securities and Exchange Commission, for the fiscal year ended December 31, 2019 ("2019 Horizon Form 10-K") at 14.

[3] *See* Horizon Press Release at https://ir.horizontherapeutics.com/news-releases/news-release-details/horizon-therapeutics-announces-significant-expansion-and.

and patents covering Krystexxa expire between 2019 and 2030, but in the United States, Krystexxa has received twelve years of biologic exclusivity, expiring in 2022.[4]

15. Horizon licenses the patents and technology for Krystexxa from Duke University, and Mountain View Pharmaceuticals, Inc.; Duke University developed the recombinant uricase enzyme used in Krystexxa and Mountain View Pharmaceuticals developed the PEGylation technology used in the manufacture of Krystexxa.[5]

16. Defendant Dr. John Botson is a doctor of internal medicine in Anchorage, Alaska specializing in rheumatology. He has been a resident of Alaska throughout the Covered Period. Dr. Botson attended Ohio State College of Medicine, in Columbus, Ohio. He completed his residency in internal medicine at Dartmouth-Hitchcock Medical Center, in Lebanon, New Hampshire. He completed a rheumatology fellowship at the National Institutes of Health, in Bethesda, Maryland and is a member of Orthopedic Physicians Alaska, located in Anchorage. Dr. Botson has written fraudulent Krystexxa prescriptions as a result of kickbacks paid to him by Horizon.

17. Defendant Orthopedic Physicians Anchorage d/b/a Orthopedic Physicians Alaska ("OPA"), is a group of orthopedic surgeons and other providers based in Anchorage and Wasilla, specializing in orthopedics, rheumatology, physical therapy, massage therapy and athletic training. OPA's principal place of business is 3801 Lake Otis Parkway, Suite 300, Anchorage, AK, 99508. Dr. Botson funneled significant volumes of fraudulent Krystexxa prescriptions to Government Programs through OPA. OPA holds NPI 1265848295.

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[4] *See* 2018 Horizon Form 10-K at 19. "While KRYSTEXXA faces limited direct competition, a number of competitors have drugs in Phase 1, or Phase 2 trials, including Selecta Biosciences Inc. who has presented clinical data from their Phase 2 study and has indicated that it plans to initiate a six-month head-to-head trial comparing their candidate to KRYSTEXXA in 2019." *Id.* at 48.

[5] *See* 2018 Horizon Form 10-K at p. 14. Duke University and Mountain View Pharmaceuticals, Inc. may terminate the agreement if Horizon commits fraud, willful misconduct or illegal conduct. *Id.*

18. Defendant Dr. Jeff Peterson is doctor of internal medicine in the State of Washington specializing in rheumatology. He has been a resident of the State of Washington throughout the Covered Period. He is board certified by the American Board of Internal Medicine with a sub-specialty in rheumatology. Dr. Peterson attended the University of Washington, in Seattle, Washington. He completed his residency in internal medicine at Internal Medicine Spokane, in Spokane, Washington. He is president of the Washington Rheumatology Alliance and director of the Northwest Rheumatism Society. Dr. Peterson is also a member of Western Washington Medical Group. Dr. Peterson has written fraudulent Krystexxa prescriptions as a result of kickbacks paid to him by Horizon.

19. Defendant Western Washington Medical Group, Inc., P.S. ("WWM") is a group of more than 100 medical providers based in the North Puget Sound Region, focusing on over 20+ specialty areas at 20 facilities in the state. WWM's principal place of business is 1728 W. Marine View Drive, Suite 110, Everett, WA 98201. Dr. Peterson funneled significant volumes of fraudulent Krystexxa prescriptions to Government Programs through WWM. WWM's internal medicine rheumatology group holds NPI 1093933491.

III. JURISDICTION AND VENUE

20. This Court has subject matter jurisdiction over Relator's FCA and AKS claims. The United States District Courts have exclusive jurisdiction over actions brought under the FCA pursuant to 31 U.S.C. § 3732, and otherwise have jurisdiction over federal statutory causes of action under 28 U.S.C. § 1331 and 1345. This Court has jurisdiction over Relator's state and common law claims pursuant to 28 U.S.C. § 1367.

21. Jurisdiction and venue are proper in this Court pursuant to the False Claims Act, 31 U.S.C. § 3732(a), because Relator's claims seek remedies on behalf of the United States for

multiple violations of 31 U.S.C. § 3729, *et seq.* in the United States by all or any one of Defendants, some of which occurred in the Southern District of New York, and because all or any one of Defendants transact other business within the Southern District of New York.

22. All Defendants are subject to the general and specific jurisdiction of this Court.

23. As a result of Horizon's organizational structure, Horizon Therapeutics PLC has continuous and systematic contacts with the United States through its contacts with its American subsidiaries.

24. This Court also has jurisdiction over actions brought under the laws of the various states since this action arises from the same transactions or occurrences. 31 U.S.C. § 3732 (b).

25. Under the FCA, this Complaint is to be filed *in camera* and remain under seal for at least 60 days unless the Court orders otherwise.

IV. RESPONDEAT SUPERIOR AND VICARIOUS LIABILITY

26. Any and all acts alleged herein to have been committed by any or all of the Defendants were committed by said Defendants' officers, directors, employees, representatives or agents who at all times acted on behalf of their respective Defendant(s) and within the course and scope of their employment.

27. The Horizon Defendants are related entities sharing common employees, offices and business names such that they are joint and severally liable under legal theories of *respondeat superior*. Further, the past, present and continuing relations and dealings by and between these related entities are so inextricably intertwined that for purposes of this suit, some or all of them can and should be considered as a single entity at law and equity.

28. Horizon Therapeutics PLC wholly owns and controls Horizon Therapeutics USA, Inc. – Relator's employer – and Horizon Medicines LLC; Horizon Ophthalmology, Inc.; Horizon

Orphan Holdings LLC; Horizon Orphan LLC; Horizon Pharma Rheumatology LLC; Horizon Therapeutics, LLC; Horizon Therapeutics Services LLC; Horizon Therapeutics, Inc.; and HZNP USA LLC, all of which are based in the United States.

29. Horizon, founded in 2008 and public since 2011, is a large multinational group of companies that engage or have engaged in a variety of business activities, including developing, marketing, and selling pharmaceutical products, all of which is, or was, accomplished through Horizon's operating groups, subsidiaries, officers, directors, employees, and agents. Horizon's subsidiaries include holding companies, operating groups and regional companies, for the most part generally organized by location, including companies operating throughout the United States. The functions of these operating groups and regional companies overlap.

30. Horizon Therapeutics USA, Inc., is an American, wholly-owned subsidiary of Horizon Therapeutics Plc which oversees and coordinates the activities of Horizon's business in the United States. For example, on January 21, 2020 a press release issued on Horizon Therapeutic's website announcing the FDA's approval of Tepezza for the treatment of thyroid eye disease, states that the media and investors may contact persons in Ireland and in the United States. Thus, Horizon Therapeutics PLC approves and directs the marketing activities of Horizon Therapeutics USA, Inc. and other American subsidiaries. Horizon Therapeutics PLC also paid the kickbacks alleged in this Complaint.

V. RELEVANT STATUTORY SCHEMES

A. The FDA's Role in the Regulation of Prescription Drugs

i. FDA Approval of Prescription Drugs

31. The FDA regulates use of pharmaceutical drugs such as Krystexxa. Companies seeking to introduce new drugs for human use into interstate commerce must comply with FDA statutes and regulations, such as the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21

U.S.C. § 301, *et seq*. The FDCA prohibits companies from distributing in interstate commerce any drugs that the FDA has not approved as safe and effective. 21 U.S.C. § 355(a) and (b).

32. In order for a company to gain approval of a drug by the FDA, the company must first submit and receive approval of a New Drug Application ("NDA") pursuant to 21 U.S.C. § 355. The company is required to include in its NDA all intended uses proposed for a new drug's labeling and to prove the new drug is safe and effective for those uses. 21 U.S.C. § 355(b). To prove that the drug is safe and effective, the company must provide the FDA with data from scientifically sound clinical trials. The FDA will refuse approval of a new drug unless, on the basis of all information reviewed, it is demonstrated that a drug can safely accomplish its purported effect under the conditions proposed, and that the method of manufacture and distribution will properly preserve the drug for this purpose. 21 U.S.C. § 355(d).

ii. FDA Regulation of Manufacturer's Marketing of Prescription Drugs

33. When the FDA reviews an NDA and approves a drug for interstate distribution, the approval is only effective for the intended uses that were proposed in the NDA and described on the drug's approved label. Any use for a drug that was not proposed in the NDA, and approved for the label by the FDA, is referred to as "unapproved" or "off-label." 65 Fed. Reg. 14286, 14286 (Mar. 16, 2000). Although physicians may prescribe a drug for an off-label use so long as the drug has been FDA-approved for some use, pharmaceutical companies are strictly prohibited from bypassing the FDA's approval process and marketing a drug off-label.

34. When a company markets a drug off-label, the drug becomes a new drug for that purpose and is considered "misbranded." *See* 21 U.S.C. § 331, 21 U.S.C. § 352(f), 21 C.F.R. § 310.3 (h)(4) and (5); *see also* 65 Fed. Reg. 14286, 14286 (Mar. 16, 2000) ("[A]n approved new

drug that is marketed for a 'new use' is also 'misbranded' under the FDCA, because the labeling of such a drug would not include 'adequate directions for use.'"). Section 352 of title 21 of the United States Code lists situations in which a drug is illegally misbranded, including but not limited to situations where: (1) the drug's labeling is "false or misleading in any particular"; (2) the drug's labeling does not bear adequate direction for use; or (3) the drug's labeling does not bear "adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users" *See* 21 U.S.C. § 352(a) and (t).

35. The term "labeling" encompasses the actual label attached to the drug's immediate container, as well as all "other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 C.F.R. § 321(m). The term has been construed to include a variety of drug company promotional materials, including booklets, pamphlets, and literature that is textually related to the product, even when disseminated without the presence of the drug. *See Kordel v. United States,* 335 U.S. 345, 349 (1948); *VE. Irons, Inc. v. United States,* 244 F.2d 34, 39 (1st Cir. 1957). In determining if a drug's labeling or advertising is misleading and thus misbranded, one must examine "(among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article" as described by the labeling or advertising or the customary or usual use of the article. 21 U.S.C. § 321(n).

36. In order for a drug's labeling (both the actual label and the promotional materials shown and given to medical professionals) to include "adequate directions for use," the directions must allow a layman to use the drug safely and for its "intended use." *See* 21 C.F.R. § 201.5. The "intended use" of a drug refers to "the objective intent of the person legally responsible for the labeling of drugs." *See* 21 C.F.R. § 201.128. "The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article," and "may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives." *Id.* Thus, if a manufacturer promotes a drug for a use for which the label does not provide adequate directions for use or is otherwise false and misleading, misbranding has occurred. This is so regardless of whether the drug is otherwise eligible for reimbursement by Government Programs.

37. Pharmaceutical manufacturers may not use reprints, reference texts or Continuing Medical Education ("CME") programs or any other devices as tools to "promote" off-label uses. Over the years, the FDA has issued regulatory guidance to aid manufacturers in distinguishing between illegal promotional strategies and the legitimate non-promotional dissemination under very specific circumstances of off-label information where it consists of genuinely scientific article reprints unedited by the manufacturer. *See, e.g.,* Guidance for the Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices, 74 Fed. Reg. 1694-01 (Jan. 13, 2009). These FDA guidance documents have never altered the FDA's long-standing prohibition against marketing and promoting approved drugs with misleading off-label information, or information that contradicts the approved FDA label.

B. Reimbursement of Prescription Drugs under Medicaid, Medicare Part B and Part D, CHAMPUS/TRICARE, CHAMPVA, FEHBP, and Other Federal Healthcare Programs

i. Medicaid

38. As a general rule, to be reimbursable under a state's Medicaid program, a drug must be included on the state's formulary. Each state has its own means of deciding coverage, but federal law sets forth requirements states must meet in excluding or restricting coverage. *See* 42 U.S.C. § 1396r--8. A state may exclude or restrict coverage of a drug in four instances:

(1) the prescribed use is not for a medically accepted indication;

(2) the drug is on the list of drugs excluded by the state from Medicaid coverage;

(3) the drug manufacturer agreed to the restrictions on the drug in its rebate agreement with Medicaid;

(4) the drug was excluded from state's drug formulary.

31 U.S.C. § 1396r-8(d)(1). In addition, states may use prior authorization programs or preferred drug lists to control potential abuses of drugs, such as prescriptions for an indication that is not a medically accepted indication.

39. A "medically accepted indication" is a use that is listed in the labeling approved by the FDA or "the use of which is *supported by* one or more citations included or approved for inclusion in" one of the drug compendia identified by the Medicaid statute. 42 U.S.C. § 1396r-8(k)(6) (emphasis added). These compendia are the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information (or its successor publications), and the DRUGDEX Information System. 42 U.S.C. § 1396r-8(g)(l)(B)(i). The United States Government and the states interpret "supported by" to require "some form of corroboration or validation." United States' Statement of Interest in Response to Defendant's Motion to Dismiss Plaintiffs First Amended Complaint, *United States ex rel. Rost v. Pfizer, Inc.*, 03-CV-11084, at p.

5 (D. Mass. May 16, 2008); *see also* Centers for Medicare and Medicaid Release No. 141 (May 4, 2006) ("The statute requires coverage of off-label uses of FDA-approved drugs for indications that *are supported (as opposed to listed)* in the compendia specified in section 1927(g)(l)(B)(II)") (emphasis added).

40. States may establish drug formularies if they meet the following requirements. *See* 42 U.S.C. § 1396r-8(d)(4). The formulary must be developed by a committee consisting of pharmacists, physicians and other qualified individuals appointed by the governor or by the state's Drug Use Review ("DUR") board consisting of healthcare professionals who have recognized knowledge and expertise in the prescription, dispensing and monitoring of outpatient drugs, drug use review, and medical quality assurance. 42 U.S.C. § 1396r-8(d)(4)(A) and § 1396r-8(g)(3).

41. The formulary must include every drug for which a manufacturer has entered into a Medicaid rebate agreement. 42 U.S.C. § 1396r-8(d)(4)(B). The state may, however, exclude a drug from the formulary if: (1) the drug is used for an on-label use -- or an off-label use that is a medically accepted indication based on compendia -- but the drug does not have a significant, clinically meaningful therapeutic advantage over other drugs on the formulary; and (2) the state provides a written explanation, which is available to the public, of why the drug is excluded. 42 U.S.C. § 1396r-8(d)(4)(C). Finally, any drugs excluded from the formulary must nevertheless be available to Medicaid enrollees under a prior authorization program. 42 U.S.C. § 1396r-8(d)(4)(D).

42. States generally have some method for drug manufacturers to request that its drug be added to the states' "preferred drug lists." In the majority of states, the Pharmaceutical and Therapeutics committee or the DUR board make the decision on whether to add drugs to the

state Medicaid program's preferred drug list. Generally, these committees announce that they will conduct a review of a class of drugs. At that time, a drug manufacturer may submit information to the committees to be considered for the drug list. A minority of states, such as Indiana, Montana, Nevada and Texas, require drug manufacturers to submit an application to be placed on the drug list. As part of the Texas application, drug manufacturers are required to expressly certify compliance with all laws, regulations and rules applicable to the Medicaid program, including the federal and state Anti-Kickback statutes. The Standard Medicaid Provider Agreement, the Standard Medicare Provider Agreement and Health Insurance Claim Form 1500, used for submission of Medicaid, Medicare, and TRICARE/CHAMPUS claims also requires compliance with "all applicable Medicare and/or Medicaid laws, regulations and program instructions for payment including but not limited to the Federal anti-kickback statute." *See* https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf

43. Pharmaceutical Therapeutics Committees and DUR boards are required to continually "assess data on drug use against predetermined standards," using the compendia as the source for these standards. 42 U.S.C. § 1396r-8(g)(l) and (2). These standards include but are not limited to monitoring for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, drug-drug interactions. *Id.* The States' continual assessment of drug data permits them the flexibility to determine the appropriate scope, duration, and limitations on coverage of drugs on their formularies.

ii. Medicare Part B and Medicare Part D

44. Medicare Part B is a federal program meant to subsidize the costs of medically necessary services such as doctors' services, some preventative services, ambulance services, durable medical equipment and outpatient care. Part B also provides supplemental benefits to

participants to cover, among other things, prescription drugs. *See generally id.* §§ 1395j-l 395w-6.

45. Medicare Part B statutes can be found at 42 U.S.C. §§ 1395j–1395w-6 and the regulations are located at 42 C.F.R. Part 414. The policy manuals can also be found at https://www.cms.gov/regulations-and-guidance/guidance/manuals/internet-only-manuals-ioms-items/cms018912.html

46. Medicare Part B was designed to create supplementary medical insurance for aged and disabled individuals who elect to enroll under this voluntary program, to be financed from premium payments by enrollees together with contributions from funds appropriated by the Federal Government. 42 U.S.C. § 1395j and § 1395l.

47. Every individual who is entitled to hospital insurance benefits under Medicare Part A, 42 U.S.C. §§ 1395c, *et seq.*, or has attained age 65 and is a resident of the United States, and is either a citizen or an alien lawfully admitted for permanent residence who has resided in the United States continuously during the 5 years immediately preceding the month in which he applies for enrollment under this part, 42 U.S.C. §§ 1395j, *et seq.*, is eligible to enroll in Medicare Part B.

48. Administration of Medicare Part B is conducted through contracts with Medicare administrative contractors. 42 U.S.C. § 1395u. Additionally, the Federal Government may enter into an agreement with a State pursuant to which all eligible individuals in either of the coverage groups will be enrolled under Medicare Part B. 42 U.S.C. § 1395v.

49. Under Medicare Part B, reimbursement is prohibited if the item or service is not "reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A).

50. Pursuant to 42 C.F.R. § 414.36, payment for drugs incident to a physician's service under Medicare Part B are made in accordance 42 C.F.R. § 405.517.

51. Medicare Part B covers physician administered drugs in an outpatient setting, and covered Krystexxa at issue in this matter for all relevant times.[6]

52. Medicare Part D is a federal program meant to subsidize the costs of prescription drugs for Medicare beneficiaries. It was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and went into effect on January 1, 2006. Part D only covers prescription drugs and will not assist with any other medical procedure. Among those individuals eligible for Medicare Part D are individuals with dual-eligibility, i.e., beneficiaries enrolled in both Medicare and Medicaid, who prior to 2006 had received outpatient drug benefits though Medicaid. Although Medicare Part D is a component of Medicare, each of the fifty states and the District of Columbia are required to make a contribution to the United States government to defray a portion of the cost of Medicare Part D for beneficiaries whose Medicaid drug coverage has been assumed by Medicare Part D. 42 C.F.R. § 423.910(a) (2008).

53. A Medicare beneficiary enrolled in Medicare Part D chooses a Prescription Drug Plan ("PDP"), which is administered by a private insurance company, or "sponsor," based upon the beneficiary's specific drug requirements. Part D sponsors are required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 to offer, at a minimum, a basic prescription drug benefit that is either the standard prescription drug benefit or is actuarially equivalent to the standard benefit. The standard costs structure makes beneficiaries responsible

[6] Medicare Part B generally does not cover prescription drugs used at home. It does, however, cover a limited number of outpatient prescription drugs under limited conditions. Generally, drugs covered under Part B are drugs a patient would not administer himself. These include drugs administered by a physician in an office or hospital outpatient setting.

for certain costs, which may include a monthly premium, an annual deductible, and coinsurance.

54. In 2018, for example, the standard drug benefit had a beneficiary deductible of $405. In the initial phase of the Part D benefit, after beneficiaries paid the deductible, they contributed twenty-five percent coinsurance toward their drug costs and the plan paid the remaining seventy-five percent until combined beneficiary and plan payments reached $3,750. After combined payments reached $3,750, beneficiaries entered the coverage gap phase of the benefit, or "donut-hole," in which they were responsible for 100 percent of their drug costs. The catastrophic coverage phase began when a beneficiary's out-of-pocket costs reaches $5,000. This amount included a beneficiary's deductible and coinsurance payments. Once beneficiaries reached $5,000 in out-of-pocket costs, they contributed approximately five percent in coinsurance toward their drug costs. Of the remaining ninety-five percent of drug costs, the Part D sponsors are responsible for approximately fifteen percent while Medicare pays eighty percent.

55. Before the beginning of the plan year, sponsors are required to submit a bid for each plan that they intend to offer. The bid is an estimate of the average costs to provide the basic benefit per beneficiary. Throughout the year, the Centers for Medicare & Medicaid Services ("CMS") makes prospective payments to sponsors for three subsidies based on sponsors' approved bids. These subsidies are: (1) the direct subsidy, (2) the reinsurance subsidy, and (3) the low-income cost-sharing subsidy. The direct subsidy, together with beneficiary premiums, is designed to cover the sponsor's cost of providing the benefit to each beneficiary. The reinsurance subsidy covers the Federal Government's share of drug costs for beneficiaries who have reached catastrophic coverage. The low-income cost-sharing subsidy covers the

Federal Government's portion of the cost-sharing payments for certain low-income beneficiaries. At the end of the plan year, CMS reconciles these prospective payments with the actual costs incurred by the plan sponsors

56. All Part D plan sponsors submit data and information necessary for CMS to determine and make payment. Every time a beneficiary fills a prescription covered under Part D, plan sponsors must submit a summary called the prescription drug event ("PDE") record. The PDE record contains drug cost and payment data that enable CMS to administer the Part D benefit. Part D plan sponsors submit one PDE record each time a Part D covered drug is dispensed to its enrollees, even for those events in which enrollees have 100 percent cost sharing (i.e., they are in the coverage gap or deductible phase).

57. CMS uses the National Council for Prescription Drug Programs industry standard for collecting PDE data. The PDE data contain information on the beneficiary, plan, pharmacy, and prescribing physician, as well as information about the event, including the date, quantity dispensed, number of days supplied, national drug code, control number, and the amount reimbursed to the pharmacy by the plan.

58. Part D covered drugs are defined as drugs available only by prescription, which are used and sold in the United States and used for a medically accepted indication, biological products, insulin and vaccines. *See* 42 C.F.R. § 423.100. Medicare Part D's definition of a "medically accepted indication" is the same as Medicaid's. *See* 42 C.F.R. § 423.100, 42 U.S.C. §§ 1396r-8 (g)(l)(B)(i) and (k)(6). Part D sponsors are responsible for ensuring that covered Part D drugs are prescribed for "medically accepted indications." Some Part D sponsors use prior authorization programs to ensure such compliance. Krystexxa is listed on PDP formularies for

Medicare Part D and is reimbursable under Medicare Part D plans across the country.

59. Before participating in government-funded healthcare programs, Defendants and other such providers are required to certify compliance with Medicare's rules and regulations, including but not limited to, the Federal Anti-Kickback Statute. Thereafter, each time Defendants or any other such provider submits a claim for payment, it is required to recertify its continued compliance.

60. When enrolling with Medicare, a provider must sign an initial enrollment application and periodically submit new applications as part of the revalidation process. Certification Statement, Sec. 5, CMS Form 855, Medicare Enrollment Application, Institutional Providers, *available at* https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms855a.pdf. As part of its agreement with Medicare, a provider certifies the following:

> I have read and understand the Penalties for Falsifying Information, as printed in this application. I understand that any deliberate omission, misrepresentation, or falsification of any information contained in this application or contained in any communication supplying information to Medicare, or any deliberate alteration of any text on this application, may be punishable by criminal, civil, or administrative penalties including, but not limited to, the denial or revocation of Medicare billing privileges, and/or the imposition of fines, civil damages, and/or imprisonment.
>
> * * *
>
> I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions . . . , and on the provider's compliance with all applicable conditions of participation in Medicare.
>
> * * *
>
> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

Id.

61. After its initial certification, a provider has an ongoing duty to notify Medicare if anything on the form becomes untrue or inaccurate:

> If I become aware that any information in this application is not true, correct, or complete, I agree to notify the Medicare fee-for-service contractor of this fact in accordance with the time frames established in 42 C.F.R. § 424.516(e).
>
> * * *
>
> I agree to notify the Medicare contractor of any future changes to the information contained in this application in accordance with the time frames established in 42 C.F.R. § 424.516(e).

Id.

62. In addition to the initial and ongoing certifications, each time a provider submits a claim, electronically or otherwise, the submission must state, in boldface type, immediately preceding the claimant's signature:

> **"This is to certify that the foregoing information is true, accurate, and complete."**
>
> **"I understand that payment of this claim will be from Federal and State funds, and that any falsification, or concealment of a material fact, may be prosecuted under Federal and State laws."**
>
> 42 C.F.R. § 455.18(a) (emphasis added). Medicare Claims Processing Manual, Ch. 24 § 30.2 A, *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c24.pdf

63. For each individual claim for payment, Defendants and other such healthcare providers must submit a CMS Form 1450, which reflects the name of the patient, the type of service provided, the total charges, and the date of the service. CMS Form 1450 requires the provider to certify its understanding "that misrepresentation or falsification of essential information . . . requested by [the form] may serve as the basis for civil monetary penalties and

assessments and may upon conviction include fines and/or imprisonment under federal and/or state law(s)" and that the provider "did not knowingly or recklessly disregard or misrepresent or conceal material facts." UB-04 Uniform Bill, CMS Form 1450 (03/01/2007), *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1104CP.pdf.

iii. CHAMPUS/TRICARE, CHAMPVA, and FEHBP

64. In addition to Medicaid, Medicare Part B, and Medicare Part D, the federal and state governments reimburse a portion of the cost of prescription drugs under several other federal and state health care programs, including but not limited to CHAMPUS/TRICARE, CHAMPVA, and Federal Employees Health Benefit Program ("FEHBP").

65. The Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") and TRICARE, a continuation of CHAMPUS, are federally funded uniformed services health care programs for active duty and retired service members, members of the National Guard and Reserve, service members' families, survivors of service members, and certain former spouses of service members. The Civilian Health and Medical Program of the Department of Veterans Affairs ("CHAMPVA"), is a federally funded healthcare program for the families and survivors of veterans who have been rated permanently and totally disabled for a service-connected disability and for the survivors of a military member who died in the line of duty, not due to misconduct. FEHBP is administered by the Office of Personnel Management and provides health insurance for federal employees, retirees, and survivors. Coverage of prescription drugs under these programs is similar to coverage under the Medicaid program. *See, e.g.*, 32 C.F.R. §§ 199.2 and 199.4(g)(15)(i); TRICARE Policy Manual 6010.54-M,

Chapter 8, Section 9.1(8)(2) (August 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II.

C. Prohibition of Kickbacks Associated with Medicaid, Medicare, CHAMPUS/TRICARE, CHAMPVA, and FEHBP

i. Federal Anti-Kickback Statute

66. The Medicare-Medicaid Anti-Fraud and Abuse Amendments, known as the Medicare Anti-Kickback Statute ("Anti-Kickback Statute"), 42 U.S.C. § 1320a-7b(b), make it illegal for an individual knowingly and willfully to offer or pay remuneration in cash or in kind to induce a physician to order a good or service that is reimbursed by a federal healthcare program. *See* 42 U.S.C. § 1320a-7b(b)(2). "Remuneration" is broadly defined to include anything of value offered or paid in return for purchasing, ordering, or recommending the purchase or order of any item reimbursable by a federal healthcare program. *See* Department of Health and Human Services, Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23734, 23737 (May 5, 2003).

67. Specifically, in pertinent part, the Anti-Kickback Statute provides:

> (b) Illegal remuneration
>
> 1. whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind-
>
> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b). Those who violate the statute also are subject to exclusion from participation in federal health care programs, and civil monetary penalties of up to $50,000 per violation and up to three times the amount of remuneration paid. 42 U.S.C. § 1320a-7(b)(7) and 42 U.S.C. § 1320a-7a(a)(7).

68. The purpose of the Anti-Kickback Statute is to prohibit such remuneration in order to secure proper medical treatment and referrals and to limit unnecessary treatment, services, or goods that are based not on the needs of the patient but on improper incentives given to others, thereby limiting the patient's right to choose proper medical care and services. *See* Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions, 54 Fed. Reg. 3088, 3089 (proposed Jan. 23, 1989) (to be codified 42 C.F.R. pt. 1001) ("[I]t is necessary for the fiscal integrity of the Medicare and Medicaid programs to assure that physicians exercise sound, objective medical judgment when controlling admittance [of new drugs and medical devices] to ... the medical marketplace.").

69. In accordance with the Anti-Kickback Statute, Medicare and Medicaid regulations directly prohibit any provider from receiving remuneration paid with the intent to induce referrals that takes into account the "volume or value" of any referrals or business generated. *See* 42 C.F.R. § 1001.952(f)(2). Such remuneration amounts to a kickback and can increase the expenditures paid by government-funded health benefit programs by leading to over-utilization of prescription drugs and/or inducing medically unnecessary and excessive reimbursements. Kickbacks also effectively reduce patients' healthcare choices, because unscrupulous (or unknowing) physicians steer their patients to various products based on the physician's own interests rather than the patients' medical needs.

70. The Medicare and Medicaid Patient and Program Protection Act of 1987 authorizes the exclusion of an individual or entity from participation in the Medicare and Medicaid programs if it is determined that the party has violated the Anti-Kickback Statute. In addition, the Balanced Budget Act of 1997 amended that Act to impose an administrative civil monetary penalty for Anti-Kickback Statute violations: $50,000 for each act and an assessment of not more than three times the amount of remuneration offered, paid, solicited or received, without regard to whether a portion of such remuneration was offered, paid, solicited or received for a lawful purpose. *See* 42 U.S.C. § 1320a-7a(a)(7).

71. Paying kickbacks taints an entire prescription, regardless of the medical propriety of its use. The kickback inherently interferes with the doctor-patient relationship and creates a conflict of interest, potentially putting the patient's health at risk. Any defendant convicted under the statute is automatically barred from participating in federal and federally-funded healthcare programs.

ii. OIG, PhRMA, AMA and ACCME's Guidelines on the Manufacturer- Doctor Relationship and Behaviors that Violate the Anti-Kickback Statute

72. Recognizing that the Anti-Kickback Statute has been applied broadly, the OIG has acknowledged that liability under the statute will ultimately turn on intent. *See* Department of Health and Human Services, Office of Inspector General ("OIG") Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003). In order to assist pharmaceutical manufacturers, the OIG issued a guidance in May 2003 that not only stated its interpretation of the Anti-Kickback statute, but also highlighted activities that may give rise to liability under the statute. *See id.* The OIG Guidance also directed drug manufacturers to review the Pharmaceutical Research and Manufacturers of America ("PhRMA") Code, the Accreditation Council for Continuing Medical Education ("ACCME")

standards relating to CMEs, and an ethical opinion issued in June 1992 and amended in April 2001 by the American Medical Association ("AMA") stating its guidelines to govern doctors' acceptance of gifts from pharmaceutical manufacturers. *See* AMA Opinion 8.061 (1992, amended 2001); PhRMA Code (2003); ACCME Standards (2004). All of these industry guidelines draw plain lines of demarcation for acceptable and unacceptable behavior under the Anti-Kickback statute.

73. The OIG's Guidance addressed specific practices commonly arising in the relationship between a drug manufacturer and physicians that present problems. *Id.* at 23738. Of particular concern to the OIG were "preceptorships," educational and research funding, CMEs, consulting and advisory arrangements, and gifts of more than trivial value to physicians such as entertainment, recreation, travel, and meals. *Id.* The OIG was also concerned about payments to physicians to: 1) listen to sales representatives market their drugs, 2) access marketing web sites, or 3) perform "research" for drug manufacturers. *Id.*

74. The AMA, PhRMA and ACCME guidelines have suggested similar limits on pharmaceutical activities. Where the three guidelines share the same perspectives on improper activities, one can presume these activities are likely to violate the federal Anti-Kickback statute.[7]

75. The issuance of these guidelines by the OIG, AMA, PhRMA and ACCME, in addition to the enactment of the Anti-Kickback Statute itself, demonstrates that federal and state health care programs consider compliance with the Anti-Kickback Statute a prerequisite to receiving or retaining reimbursement payments from Medicaid, Medicare Part B, Medicare Part D, and other federal health care programs.

[7] The three guidelines all address several pharmaceutical activities, such as gifts, entertainment, conferences, CMEs, and consultants. The ACCME standards address only CME activities.

76. AMA policy states that "[t]o avoid the acceptance of inappropriate gifts, physicians should observe the following guidelines:

> (1) Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. . . . Cash payments should not be accepted.
>
> (2) Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (e.g., pens and notepads).
>
> * * *
>
> (7) No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician's prescribing practices. In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences or lectures.

American Medical Association, Council on Ethical and Judicial Affairs, "Gifts to Physicians from Industry," AMA Ethical Opinion 8.061

77. AMA policy also prohibits physicians from accepting "any kind of payment or compensation from a drug company . . . for prescribing its products." *See* AMA Ethical Opinions 6.04 (Fee Splitting); *see also* AMA Ethical Opinion 6.02 (Fee Splitting).

78. The American College of Physicians' Ethics Manual ("Ethics Manual") recognizes "drug industry gifts" as having potentially negative influence on clinical judgment and notes that it is "unethical for a physician to receive a commission or a kickback from anyone, including a company that manufactures or sells . . . medications that are used in the care of the physician's patients." *See* Ethics Manual, Financial Conflicts of Interest. Free or discounted equipment or services to physicians are "suspect" under the CMPL, 42 U.S.C. § 1320a; Office of Inspector General Guidance, COMPLIANCE PROGRAM GUIDANCE FOR PHARMACEUTICAL MANUFACTURERS, 68 Fed. Reg. 86 at 23731 (hereinafter, "OIG Guidance.").

79. Free or discounted equipment or services, such as computers, faxes or business management consulting services to physicians are "suspect" under the Anti-Kickback Statute, 42 U.S.C. §1320(a), *et seq.*, as are educational grants and payments to physicians for consulting services. *See* Office of Inspector General Guidance, Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 86 at 23731) (hereinafter, "OIG Guidance.").

80. Research contracts that originate through the sales and marketing functions—or that are offered to doctors in connection with sales contacts—are particularly suspect under the Anti-Kickback Statute. *See* OIG Guidance, 68 Fed. Reg. at 23738. Most dubious in this regard is research that is initiated or directed by the sales or marketing agents that is not transmitted to the manufacturer's science division. *Id.*

VI. HORIZON'S SCHEME TO SELL KRYSTEXXA THROUGH OFF-LABEL MARKETING AND ILLEGAL KICKBACKS

A. Relator's Background & Summary

81. In her professional capacity, Relator directly witnessed Horizon, after the FDA refused to let Horizon alter its safety warning label, engage in misbranding and off-label promotion, which included, but was not limited to, the use of false and misleading promotional materials using off-label data to deceptively downplay the risks of Krystexxa and engaging in kickbacks to the highest prescribers of Krystexxa to maintain and drive sales.

82. Since at least 2016 and continuing to the present, Defendant Horizon has engaged in a systematic practice to boost sales of Krystexxa illegally. Horizon's illegal activity includes manipulating the clinical trial data and fraudulently downplaying the risks of Krystexxa in promotional material to increase sales; deploying its marketing team to ghostwrite the content of a "scientific" article about Krystexxa in order to mislead prescribers and increase sales; using sham advisory "safety boards" to meet with doctors and communicate misleading off-label data

to them; and paying kickbacks to the highest prescribers to ensure unusually high sales of the drug.

83. As part of their fraudulent scheme, Defendants knowingly provided false information regarding the efficacy and risk of Krystexxa which caused physicians and pharmacists to either expressly or impliedly make false certifications about Krystexxa's appropriateness or necessity for patients' treatment. Defendants' intent was to give prescribing physicians a false sense of security to tip the balance between safety risks and benefits in favor of the treatment, and therefore increase sales of the drug. As a result of their fraudulent scheme, Defendants have caused the submission of false claims for Krystexxa prescriptions that were paid for by Medicare, Medicaid, TRICARE and CHAMPVA, and private insurers, as medically necessary, and these programs and payors have spent millions on fraudulent claims for Krystexxa prescriptions – generating more prescriptions and more profits for Defendants.

B. Chronic Gout & Krystexxa Overview

i. Chronic Gout Refractory to Conventional Therapy

84. Krystexxa, the drug at issue in this case, is indicated for use by patients who have chronic gout and are unable to control their disease with conventional therapy (commonly prescribed oral medications). Chronic gout is a disease characterized by high levels of uric acid in the body. Increased uric acid can accumulate and result in debilitating deposits anywhere in the body including the bones, joints, and tendons. The condition can result in debilitating joint inflammation and severe pain.

85. Gout can result in gout attacks or flares. According to the Johns Hopkins Arthritis Center, "[a] typical gout attack is characterized by the sudden onset of *severe* pain, swelling, warmth, and redness of a joint. . . the joint most commonly involved in gout is the first

metatarsophalangeal joint (the big toe), and is called podagra. Any joint may be involved in a gout attack (and it may be more than one) with the most frequent sites being in the feet, ankles, knees, and elbows. An acute gout attack will generally reach its peak 12-24 hours after onset, and then will slowly begin to resolve even without treatment. Full recovery from a gout attack (without treatment) takes approximately 7-14 days. . . For some patients, gout can result in recurrent attacks. In more severe cases, there can be short intervals between attacks, or incomplete resolution of inflammation between attacks. This form of severe, uncontrolled gout, can cause significant joint destruction and deformity and may be confused with other forms of chronic inflammatory arthritis such as rheumatoid arthritis."[8]

86. Additionally, gout can result in tophi. "Tophi are chunks of uric acid (monosodium urate) crystals that accumulate in and around joints and other parts of the body as the result of advanced gout. A tophus around a joint can cause it to become swollen and misshapen and the skin that covers it to become stretched and taut, sometimes to the point of ulceration. Tophi can erode bone and destroy cartilage, leading to chronic inflammation that can be painful and debilitating. A tophus typically is easy to identify with a visual exam, but sometimes imaging or aspiration may be necessary to confirm a diagnosis. Depending on the size and location of a tophus, it can be dissolved/diminished with medication that lowers the levels of uric acid in the blood, like oral urate lower therapies that are the first line of treatment, or Krystexxa. In the instance of very large tophi, surgical removal is sometimes undertaken. Tophi affect 12% to 35% of people with gout."[9]

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[8] *See https://www.hopkinsarthritis.org/arthritis-info/gout/clinical-presentation-of-gout/*

[9] *See https://www.verywellhealth.com/gout-tophi-tophus-what-is-it-189830*

87. According to WebMD, gout affects 8.4 million people in the U.S. or roughly 4% of the population.[10] It is estimated that refractory gout affects about 1% of the overall gout patients in the United States – approximately, 84,000 people nationwide. Horizon estimates that greater than 100,000 patients have uncontrolled gout, or less than 0.0003% of the population.

88. According to the Centers for Disease Control and Prevention ("CDC"), "Gout is caused by a condition known as hyperuricemia, where there is too much uric acid in the body. The body makes uric acid when it breaks down purines, which are found in the body and in the foods we eat. When there is too much uric acid in the body, uric acid crystals (monosodium urate) can build up in joints, fluids, and tissues within the body. Hyperuricemia does not always cause gout, and hyperuricemia without gout symptoms does not need to be treated." *See* https://www.cdc.gov/arthritis/basics/gout.html

89. The CDC states that "Gout can be effectively treated and managed with medical treatment and self-management strategies." Health care providers may recommend a medical treatment plan to (a) Manage the pain of a flare (treatment for flares consists of nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen, steroids, and the anti-inflammatory drug colchicine; (b) Prevent future flares (by making changes to diet and lifestyle, such as losing weight, limiting alcohol, eating less purine-rich food (like red meat or organ meat), may help prevent future attacks; changing or stopping medications associated with hyperuricemia (like diuretics) may also help); (c) Prevent tophi and kidney stones from forming as a result of chronic high levels of uric acid. Tophi are hard, uric acid deposits under the skin. For people with frequent acute flares or tophi, doctors may recommend preventive therapy to lower uric acid levels in the blood using drugs like allopurinol, febuxostat, and, when oral therapies have

[10] *See https://www.webmd.com/arthritis/news/20110728/gout-becoming-more-common-in-us*.

failed or are contraindicated, pegloticase (Krystexxa). In addition to medical treatment, gout can be treated with self-management strategies, day to day strategies to manage the condition and stay healthy, like making healthy lifestyle choices, physical exercise, and losing weight.

90. According to Horizon, "Uncontrolled gout occurs in patients who have failed to normalize serum uric acid, or sUA, and whose signs and symptoms are inadequately controlled with conventional therapies, such as xanthine oxidase inhibitors, or XOIs, at the maximum medically appropriate dose, or for whom these drugs are contraindicated."[11]

ii. Krystexxa

91. Krystexxa (scientific name *pegloticase*), manufactured and marketed by Horizon, is an "orphan" drug originally developed by Savient Pharmaceuticals and approved for use in the United States by the FDA in 2010. Savient was unable to launch the medication successfully and struggled with slow sales growth, which eventually led Savient to bankruptcy. Savient sold its assets to Crealta Pharmaceuticals in a bankruptcy fire sale in 2013. In 2016, Horizon acquired Crealta Pharmaceuticals and all of its assets, including Krystexxa.[12] During its first year on the market, the company which developed the drug, Savient Pharmaceuticals, priced Krystexxa at about $2,300 per dose, with a bi-weekly 6-month treatment costing an estimated $27,000, or $54,000 per year. Horizon charges approximately $250,000 a year for treatment with Krystexxa, or approximately $125,000 for a bi-weekly, 6-month regimen – a 600% increase above Savient's initial price. According to CMS's Medicare Drug Spending Dashboard, in 2018, Medicare's Part B average spending per beneficiary for Krystexxa was $116,588.00; and Medicare Part B spent a

[11] *See* 2019 Horizon Form 10-K at p. 5.

[12] *See* 2018 Horizon Form 10-K at p. 3 ("On January 13, 2016, we completed our acquisition of Crealta Holdings, LLC, or Crealta, which added the rare disease medicine KRYSTEXXA…to our medicine portfolio, or the Crealta acquisition.").

total of $72,284,678.00 on Krystexxa; similarly, in 2018, Medicare's Part D average spending per beneficiary for Krystexxa was $164,969.00; and Medicare Part D spent a total of $24,250,415.00 on Krystexxa. Medicare alone spent approximately a total of $96.5 million on Krystexxa for Medicare beneficiaries in 2018. According to CMS's Medicare Drug Spending Dashboard, in 2018, Medicaid paid $9,102,868 for Krystexxa.

92. Krystexxa is Defendant Horizon's flagship pharmaceutical. According to Horizon's annual reports, Horizon doubled sales for Krystexxa in 2017 to $156.5 million, and quadrupled them by 2018, to $258.9 million. According to Horizon's investor prospectus, in 2018, Horizon projected greater than 20% growth in 2019. Last year Horizon was aiming for target sales of greater than $750 million annually, but this year adjusted those projections up to $1 billion annually. According to Horizon's most recent SEC filing, Horizon reported $342.4 million net sales of Krystexxa in 2019.[13] Upon information and belief, Drs. Botson and Peterson account for approximately 20-25% of all sales of Krystexxa in the United States.

93. Krystexxa poses significant risks and treatment issues, however. First, the treatment is very expensive, as it costs approximately $250,000 per regimen; treatment can continue for months or years, with the optimal duration of treatment unknown. Second, the treatment poses serious health risks that may outweigh the benefits for many patients. Since Krystexxa is a foreign protein infused into the human body, it activates an immune system response that generates anti-drug antibodies; the immune system response results in a loss of efficacy (because the immune system clears the drug from the body, as the antibodies neutralize the effect of the drug); it also leads to side effects when the drug is infused or shortly thereafter

[13] *See* 2019 Horizon Form 10-K at 4.

(referred to as infusion reactions) such as skin rashes, hives, chest pain, difficulty in breathing, and life-threatening anaphylaxis.

94. According to Krystexxa's black box warning on the FDA approved label, there is a significant risk of anaphylaxis, which at its worst can lead to death, seen in 6.5% of patients, while infusion reactions generally occur in 26% of patients.

95. The high risk associated with Krystexxa and the need to administer it by intravenous infusion with continuous monitoring in an office equipped to deal with life-threatening anaphylaxis prevents many doctors from prescribing this drug. For this reason, Horizon has spent a great deal of time and energy to fraudulently downplay and minimize the risks of Krystexxa in communications with prescribers and is paying kickbacks to the highest prescribers of the drug to maintain and increase current sales levels.

96. Horizon previously sought a request to change the FDA-approved safety information on the label, which would have effectively downplayed the safety risks, but the FDA rejected that request.

a. Indication

97. According to the current label, Krystexxa, is a "PEGylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy." In other words, the FDA limited Krystexxa's approval to use in patients who have not responded to conventional therapies.

98. Allopurinol is the gold-standard treatment for gout and works by blocking the production of uric acid, reducing overall body levels. Krystexxa's label reflects Krystexxa's approval for use when the first-line choices like allopurinol, given at the maximally tolerated dose, fail. In instances in which allopurinol does not achieve the desired effect, another oral

agent that works in a similar way, febuxostat, should also be tried. Most patients will tolerate and respond to these conventional therapies.

99. Thus, Krystexxa is considered a drug of "last-resort" for otherwise untreatable gout. It is given intravenously and works differently from oral agents by directly breaking down uric acid and lowering high levels of uric acid in the body quickly; increased uric acid in the body causes gout and can result in debilitating deposits anywhere in the body including the bones, and joints. The condition can result in debilitating joint inflammation and severe pain.

b. Means of Administration and Dosage

100. Krystexxa is administered in 8 mg doses by intravenous infusion over no less than 120 minutes via gravity feed, syringe-type pump, or infusion pump, every 2 weeks. The optimal duration of treatment is unknown, but it is generally given over approximately 3 to 6-month intervals, with treatment extending up to a year or beyond based on patient response to therapy and physician discretion. Krystexxa is diluted prior to use, using 1 mL of Krystexxa into a 250 mL bag of 0.9% Sodium Chloride Injection, USP or 0.45% Sodium Chloride Injection, USP for intravenous infusion at room temperature.

101. Patients are required to discontinue oral urate-lowering agents before starting Krystexxa, so as not to mask loss of efficacy that is commonly seen with Krystexxa over time, attributed to production of antibodies against the drug. Doctors are supposed to monitor serum uric acid levels before each infusion and patients should be pre-medicated with antihistamines and corticosteroids to reduce the risk of allergic reactions, including anaphylaxis. Risks are so great that the label requires Krystexxa to be administered "in a healthcare setting by healthcare providers prepared to manage anaphylaxis."

c. Pharmacology

102. According to its label, "Krystexxa is a uric acid specific enzyme which is a recombinant uricase and achieves its therapeutic effect by catalyzing the oxidation of uric acid to allantoin, thereby lowering serum uric acid. Allantoin is an inert and water-soluble purine metabolite; it is readily eliminated, primarily by renal excretion."

103. The label states, "approximately 24 hours following the first dose of Krystexxa, mean plasma uric acid levels for subjects in the Krystexxa groups were 0.7 mg/dL for the Krystexxa 8 mg every 2 weeks group. In comparison, the mean plasma uric acid level for the placebo group was 8.2 mg/dL."

104. The label further states that "[i]n a single-dose, dose-ranging trial, following 1-hour intravenous infusions of 0.5, 1, 2, 4, 8 or 12 mg of pegloticase in 24 patients with symptomatic gout (n=4 subjects/dose group), plasma uric acid decreased with increasing pegloticase dose or concentrations. The duration of suppression of plasma uric acid appeared to be positively associated with pegloticase dose. Sustained decrease in plasma uric acid below the solubility concentration of 6 mg/dL for more than 300 hours was observed with doses of 8 mg and 12 mg."

d. Efficacy

105. According to its label, "the efficacy of Krystexxa was studied in adult patients with chronic gout refractory to conventional therapy in two replicate, multicenter, randomized, double-blind, placebo-controlled studies of six months duration: Trial 1 and Trial 2."

106. "Patients were randomized to receive Krystexxa 8 mg every 2 weeks or every 4 weeks or placebo in a 2:2:1 ratio. Studies were stratified for the presence of tophi. Seventy-one percent (71%) of the patients had baseline tophi."

107. "To assess the efficacy of Krystexxa in lowering uric acid, the primary endpoint in both trials was the proportion of patients who achieved plasma uric acid ("PUA") less than 6 mg/dL for at least 80% of the time during Month 3 and Month 6."

108. During the clinical trials, "a greater proportion of patients treated with Krystexxa every 2 weeks achieved urate lowering to below 6 mg/dL than patients receiving placebo." Notably, "[a]lthough the 4 week regimen also demonstrate efficacy . . . this regimen was associated with increased frequency of anaphylaxis and infusion reactions and less efficacy with respect to [reducing] tophi."

109. According to the clinical trial data, after six months, "the percentage of patients who achieved a complete response (defined as 100% resolution of at least one target tophus, no new tophi appear and no single tophus showing progression) was 45%, 26%, and 8%, with Krystexxa 8 mg every 2 weeks, Krystexxa 8 mg every 4 weeks, and placebo, respectively. The difference between Krystexxa and placebo was statistically significant for the every 2 week dosing regimen, but not for the every 4 week dosing regimen." The clinical trial did not reach conclusions about patients who did not achieve a complete response.

e. Safety Concerns

110. Krystexxa is not a risk-free medication and may cause several serious health risks. The Krystexxa label has a black box warning entitled, "WARNING: ANAPHYLAXIS and INFUSION REACTIONS."[14]

> **WARNING: ANAPHYLAXIS and INFUSION REACTIONS**

[14] The "black box" warning on a drug's label is the FDA's strongest warning. Such a warning, which is named a "black box" warning for the black border that surrounds the text of the warning on the prescribing information, indicates that a serious, adverse event, including death, is associated with that particular drug.

- Anaphylaxis and infusion reactions have been reported to occur during and after administration of KRYSTEXXA. (5.1, 5.2)
- Anaphylaxis may occur with any infusion, including a first infusion, and generally manifests within 2 hours of the infusion. However, delayed-type hypersensitivity reactions have also been reported. (5.1)
- KRYSTEXXA should be administered in healthcare settings and by healthcare providers prepared to manage anaphylaxis and infusion reactions. (5.1, 5.2)
- Patients should be premedicated with antihistamines and corticosteroids. (5.1, 5.2)
- Patients should be closely monitored for an appropriate period of time for anaphylaxis after administration of KRYSTEXXA. (5.1)
- Monitor serum uric acid levels prior to infusions and consider discontinuing treatment if levels increase to above 6 mg/dL, particularly when 2 consecutive levels above 6 mg/dL are observed. (5.2)

1. Anaphylaxis

111. Studies have shown that Krystexxa causes anaphylaxis, a severe potentially life-threatening allergic reaction. According to its label, "[d]uring pre-marketing controlled clinical trials, anaphylaxis was reported with a frequency of 6.5% of patients treated with Krystexxa every 2 weeks, compared to none with placebo. Manifestations include wheezing, peri-oral or lingual edema, or hemodynamic instability, with or without rash or urticaria." "The diagnostic criteria of anaphylaxis were skin or mucosal tissue involvement, and, either airway compromise, and/or reduced blood pressure with or without associated symptoms, and a temporal relationship to Krystexxa. Using these clinical criteria, anaphylaxis was identified in 5.1% of patients studied in the clinical trial: the frequency was 6.5% for the every 2-week dosing regimen, and 4.8% for the 4-week dosing regimen; and anaphylaxis generally occurred within 2 hours after treatment.

112. "Cases of anaphylaxis occurred in patients being pre-treated with one or more doses of an oral antihistamine, and intravenous corticosteroid and/or acetaminophen." As a result, "the pre-treatment may have blunted or obscured symptoms or signs of anaphylaxis and therefore the reported frequency may be an underestimate." The label also warns that "delayed-type hypersensitivity reactions have also been reported." The danger of anaphylaxis is heightened by the fact that "[a]naphylaxis may occur with *any* infusion, including the first infusion, and generally manifests within 2 hours of the infusion."

113. "The risk of anaphylaxis is higher in patients whose uric acid level increases to above 6 mg/dL, particularly when 2 consecutive levels above 6 mg/dL are observed."

114. For these reasons, the label recommends that Krystexxa be "administered in healthcare settings and by healthcare providers prepared to manage anaphylaxis" and that patients "should be closely monitored for an appropriate period of time for anaphylaxis after administration of Krystexxa." Moreover, "[p]atients should be informed of the symptoms and signs of anaphylaxis and instructed to seek immediate medical care should anaphylaxis occur after discharge from the healthcare setting."

2. Infusion Reactions

115. Studies have also shown that Krystexxa causes infusion reactions. "During pre-marketing controlled clinical trials, infusion reactions were reported in 26% of patients treated with Krystexxa 8 mg every 2 weeks, and 41% of patients treated with Krystexxa 8 mg every 4 weeks, compared to 5% of patients treated with placebo." "Manifestations of these [infusion] reactions included urticaria (frequency of 10.6%), dyspnea (frequency of 7.1%), chest discomfort (frequency of 9.5%), chest pain (frequency of 9.5%), erythema (frequency of 9.5%), and pruritus (frequency of 9.5%)." Moreover, "[t]hese manifestations overlap with the symptoms of

anaphylaxis, but in a given patient did not occur together to satisfy the clinical criteria for diagnosing anaphylaxis. Infusion reactions are thought to result from release of various mediators, such as cytokines."

116. Since these reactions occurred in patients being pre-treated with an oral antihistamine, intravenous corticosteroid and/or acetaminophen, this pre-treatment may have blunted or obscured symptoms or signs of infusion reactions and therefore the reported frequency may be an underestimate. For these reasons, "Krystexxa should be infused slowly over no less than 120 minutes. In the event of an infusion reaction, the infusion should be slowed, or stopped and restarted at a slower rate."

117. As with anaphylaxis, "the risk of infusion reactions is higher in patients whose uric acid level increases to above 6 mg/dL, particularly when 2 consecutive levels above 6 mg/dL are observed." Moreover, infusion reactions "occurred at any time during a course of treatment with approximately 3% occurring with the first infusion, and approximately 91% occurred during the time of infusion." The label also notes that the "risk of an infusion reaction is higher in patients who have lost therapeutic response."

3. *Gout Flares*

118. Studies have also shown that Krystexxa may cause gout flares. "During the controlled treatment period with Krystexxa or placebo, the frequencies of gout flares were high in all treatment groups, but more so with Krystexxa treatment during the first 3 months of treatment, which seemed to decrease in the subsequent 3 months of treatment." The reported frequency was 65% with Krystexxa 8 mg every 2 weeks.

4. Congestive Heart Failure

119. According to the label, "[t]wo cases of congestive heart failure exacerbation occurred during the trials in patients receiving treatment with Krystexxa 8 mg every 2 weeks" and "[f]our subjects had exacerbations of pre-existing congestive heart failure while receiving Krystexxa 8 mg every 2 weeks during the open-label extension study."

5. Other Adverse Reactions

120. Aside from anaphylaxis, infusion reactions, gout flares and congestive heart failure exacerbation, the most commonly reported adverse reactions that occurred in greater than or equal to 5% of patients treated with Krystexxa 8 mg every 2 weeks were nausea (frequency of 12%), contusion or ecchymosis (frequency of 11%), nasopharyngitis (frequency of 7%), constipation (frequency of 6%), chest pain (frequency of 6%), and vomiting (frequency of 5%).

C. Horizon's Off-Label Marketing Strategies and False Claims

121. Because Krystexxa is a "foreign protein" being infused into the human body, the drug tends to activate the human immune system. The vast majority of patients (over 90%) generate antibodies against the drug (anti-drug antibodies), and in nearly half of the patients the levels of anti-drug antibodies become quite elevated.[15] Anti-drug antibodies are thought to produce two main effects: (1) they reduce the effectiveness of the drug, because the antibodies neutralize its effect, resulting in a loss of efficacy; and (2) they produce side effects when the drug is infused in the presence of these anti-drug antibodies ("infusion reactions").

122. According to the prescribing information, Krystexxa is at most only effective in 45% of patients, and can cause life-threatening anaphylaxis in up to 6.5% of patients, with infusion reactions overall seen in 26% to 41% of patients receiving it. Although no fatalities

[15] *See* Lipsky et al. ARTHRITIS RESEARCH & THERAPY 2014, 16:R60.

were considered caused by the study drug during the clinical trials, the effects observed lead to considerable concern from the FDA, which required warnings about anaphylaxis and infusion reactions to be included in a "Black Box Warning" in the product's label (a black box warning is the strictest warning that can be put in the label of a prescription drug by the FDA).[16]

123. According to Relator, physicians have expressed concern about the safety profile of Krystexxa, and hesitated to use the drug, for these reasons. Not surprisingly, Horizon admitted that its "ability to generate revenues" from its medications "is subject to attaining significant market acceptance among physicians, patients and healthcare payers."[17]

124. Horizon doubled its Krystexxa commercial team in 2018 and increased "promotional efforts to further penetrate rheumatology and initiate marketing to nephrology" while "growing [its] customer base from both new and existing prescribers."[18]

125. Horizon stated publicly,

> With respect to Krystexxa, our ability to grow sales will be affected by the success of our sales, marketing and clinical strategies, which could expand the patient population and usage of Krystexxa.[19]

126. Horizon has told shareholders, "[i]f we are unable to effectively train and equip our sales force, our ability to successfully commercialize our medicines will be harmed."[20] To that end, Horizon committed to "expend significant time and resources to train [its] sales force to

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[16] Recently, at least one death of a patient using KRYSTEXXA was reported.

[17] *See* 2018 Horizon Form 10-K at 34.

[18] *See* 2019 Horizon Form 10-K at 6.

[19] *See* 2018 Horizon Form 10-K at 35.

[20] *See* 2018 Horizon Form 10-K at 37.

be credible and persuasive ***in convincing physicians to prescribe and pharmacists to dispense [its] medicines***."[21]

127. This was ultimately achieved by ghostwriting a "scientific" paper and arming the sales force with misleading promotional material and funding sham "safety boards" that used off-label misrepresentations to misbrand Krystexxa and deceive physicians about the safety and effectiveness of Krystexxa – to convince them to prescribe Krystexxa more often, when it was neither safe nor medically necessary to do so. Convincing physicians to determine that a patient had "failed" oral therapy sooner/more quickly was an objective of the sales team. Reassuring physicians about the false safety of Krystexxa was part of the scheme to encourage them to conclude that oral medications had failed and that a patient should move more quickly to Krystexxa.

i. Horizon Fails to Persuade FDA to Change Labeling for Krystexxa

128. Horizon sought but failed to obtain FDA approval to change the label for Krystexxa to reflect diminished safety risks, which would have encouraged more doctors to use the drug and increase its sales.

129. Data from the initial clinical studies used to approve Krystexxa were further reviewed for a connection between the increased risk of infusion reactions and the development of anti-drug antibodies. Monitoring a patient's uric acid levels in the blood, and detecting when those levels rose, indicated a loss of efficacy due to anti-drug antibodies, and a warning sign that the patient was at higher risk for an infusion reaction.

[21] *See* 2018 Horizon Form 10-K at 37.

130. This observation was not possible during the original clinical studies because the investigators and sponsor of the studies were blinded to the serum uric acid levels, and thus the drug was continued with no knowledge or consideration of uric acid levels.

131. Monitoring blood uric acid levels could provide information on the risk of infusion reactions. As the anti-drug antibodies are thought to increase risk of infusion reactions, the uric acid level can indicate whether these anti-drug antibodies have formed. Various re-analyses of the clinical study data were undertaken after the study ended to explore this hypothesis. In a post-hoc analysis of the data from the studies leading to the drug's approval it was appreciated that, if the drug had been stopped at the time that the uric acid increased to above a certain threshold (6 mg/dL), it appeared that many infusion reactions could have been avoided.

132. Although this observation was based on a second, post-hoc analysis, the overall finding that uric acid levels may generally guide physicians on pegloticase safety was deemed important for product labeling; according to the FDA approved U.S. Prescribing Information ("US PI") when uric acid rises to above 6 mg/dL physicians should consider stopping the infusion, particularly when two consecutive levels above 6 mg/dL are observed. However, there have been no prospective studies completed to date to assess the ***actual*** incidence of infusion reactions with the use of serum uric acid (sUA) monitoring and stopping rules, nor to establish the ***optimal*** stopping rules to be used when administering the drug. As a result, the infusion reaction rates that may be expected in clinical practice are ***unknown***, and the FDA-approved label reports only the data directly observed in the clinical trials.

133. Nevertheless, the prospect of increasing medical community awareness of the concept of "uric acid monitoring" and uric acid "stopping rules" became of great interest to

Horizon because Horizon believed that greater comfort with the safety profile of the drug would lead to greater use of the drug by physicians and increased sales of Krystexxa, despite lack of definitive data on the risks with the drug. And, while the current label provides general guidance and warnings about discontinuation when a patient's uric acid level rises, the lack of more detailed information in the labeling, on this topic, was a source of frustration for Horizon because the black box warning in the US PI contained dire warnings about the possibility of anaphylaxis – a serious life-threatening allergic reaction – requiring close monitoring during treatment with the drug.

134. The black box warning warns physicians that the blood (serum) uric acid levels should be monitored and that physicians should consider discontinuation of treatment if the levels rise to above 6 mg/dL, because this reflects a higher risk of infusion reactions. In the more detailed sections addressing safety in the prescribing information, it is noted that infusion reactions occurred at a frequency of 26% in patients treated with 8 mg Krystexxa every 2 weeks.

135. However, the label does ***not*** express any "adjusted" infusion reaction rates ***if*** uric acid monitoring and stopping rules are implemented. The greatest detail offered on this subject in the prescribing information appears in a footnote to the efficacy results presented in Section 14, titled "Clinical Studies" of the US PI, where it is noted that infusion reactions would have been reduced by approximately 67% if the drug had been stopped when a patient's uric acid level rose to greater than 6 mg/dL on a single occasion, and would have been "about half" if the drug had been stopped after 2 consecutive uric acid levels greater than 6 mg/dL, without any further detail. The FDA declined to allow inclusion of any lower rates of infusion reactions with the use of uric acid monitoring in the US PI because it was based on post-hoc data of a later study that ***was not designed to determine these rates with confidence.***

136. Horizon had a strong commercial interest in communicating lower risks of infusion reactions to doctors, whether they were valid or not, because lower risks of infusion reactions would persuade doctors to use the drug more often and increase its sales. Horizon requested a label update from the FDA to include additional data on infusion reactions in the US PI. The key data the Company sought to include was another post-hoc analysis on infusion reaction rates with the use of serum uric acid stopping rules, undertaken by the Company, and different from the original post-hoc analysis that led to product labeling, with even more favorable infusion reaction rates than in the post-hoc analysis that informed labeling. The Horizon post-hoc analysis attempted to simulate what would have happened if serum uric acid stopping rules were followed using serum acid levels drawn immediately before each infusion (rather than based on uric acid levels from the prior clinic visit, two weeks before the infusion, as in the first post-hoc analysis), with patients taken off the drug if their serum uric acid rose to above 6 mg/dL on one or two consecutive occasions.

137. The post-hoc analysis suggests that, in the trials that led to approval, if patients had been taken off the drug when they had one uric acid level greater than 6 mg/dL checked in the morning prior to the infusion of the drug, there would have been infusion reactions seen in 2% of patients. If a patient was discontinued after two uric acid levels > 6 mg/dL checked in the morning prior to the infusion of the drug, there would have been infusion reactions seen in 8% of patients. While this data was scientifically interesting, it was generated in a post-hoc fashion and based on a study that was ***not*** prospectively designed to answer the question of how best to perform uric acid monitoring, to identify what stopping rules should be used, and to ascertain the expected rates of infusion reactions with the implementation of that monitoring. According to Relator, it was common knowledge on the Horizon extended team consisting of Clinical

Development, Medical Affairs, and Marketing that these data had been specifically presented to the FDA with a request for inclusion in labeling and that this request was rejected by the FDA, in part because the methodology of the study was not acceptable to the FDA. Notably, the FDA approved label reports that 3% of infusion reactions occurred at the first infusion, when stopping rules do not apply. Thus, the assertion that stopping rules will lead to infusion reactions in only 2% of patients is particularly misleading, as this is below the frequency of infusion reactions expected with the very first infusion of the drug.

138. Dr. Paul Peloso (Vice President of Clinical Development, in the Therapeutic Area and Head for Rheumatology), was familiar with these discussions and stated that the decision was made by the FDA that this post-hoc analysis data did not meet the standard for labeling. As a result, Horizon then sought other ways to communicate the off-label data in promotional settings, despite specific feedback from the FDA that this data did not meet the required standard for labeling, and despite the fact that it would give doctors a false sense of security and put patients' health at risk.

ii. Horizon's Duplicitous Medical Journal Publication

139. After the FDA denied approval to alter the label prescribing information, Horizon decided to disregard the FDA's ruling and increase sales by misrepresenting the efficacy of Krystexxa and downplaying its safety risks. Horizon commenced its fraudulent scheme by ghostwriting the content of a scientific article published in a medical journal with the primary intent of citing it in Krystexxa promotional and marketing material that would be shown to doctors. The purpose of the article was to give the false impression that the claims in the marketing material were supported by independent science and research. The Krystexxa marketing team directed the writing and content of the article. External authors of the article may not have been aware of the role of the marketing team in shaping the content.

140. The "scientific" article, *Use of Infusion Serum Uric Acid Levels as a Biomarker for Infusion Reaction Risk in Patients on Pegloticase*, published in early 2019 in the journal Rheumatology and Therapy, was authored by Horizon's Director of Medical Affairs, Brian LaMoreaux, who owns stock in the company, and two external authors.

141. The article reads like promotional material rather than a medical journal article; it contains post-hac data analyses showing a lower incidence of side effects, the same information which was specifically rejected by the FDA for labeling. In fact, Relator learned that the marketing team at Horizon ghostwrote the article by controlling its scope and content, they edited the language painstakingly, and especially directed the focus of the article towards the unsupported 8% and 2% risk rates that would be highlighted in the upcoming false promotional material. Equally important, Relator learned the article was intended to serve as a promotional tool by sales representatives when selling to prescribing physicians in the field and to be printed out and left behind in physicians' offices, lending credibility to the false claims Horizon was planning to circulate in deceptive promotional material.

142. The misleading messaging of the ghostwritten article begins with the abstract. In the abstract, the authors write: "if pegloticase therapy was stopped after a single pre-infusion sUA above 6 mg/dL, only two patients (2%) would have experienced IRs during the clinical studies".[22] This is plainly false because the data in the prescribing label clearly indicates that, in the clinical studies, "infusion reactions occurred at any time during a course of treatment with approximately 3% occurring with the first infusion."[23] Contradicting the risk established by the

[22] LaMoreaux et al. *Use of Infusion Serum Uric Acid Levels as a Biomarker for Infusion Reaction Risk in Patients on Pegloticase*, RHEUMATOLOGY AND THERAPY 2019 at p. 299.

[23] USPI, Section 5.2, Infusion Reactions, p.4

label, the ghostwritten article in effect promises a lower rate of infusion reactions over the course of treatment than was observed *with the first infusion*, per the label.

143. The article also falsely indicates that, in the less conservative scenario of stopping Krystexxa therapy after two consecutive pre-infusion sUA levels above 6 mg/dL, "only seven (8%) would have had IRs [infusion reactions]." This is far below the rate from the label, which indicates that the "incidence of infusion reactions would have been half" of the 26% of infusion reactions under this scenario, i.e. approximately 14% - not 8% as the article misrepresents.

144. It should be acknowledged that the analysis that was undertaken in the ghostwritten article was not itself invalid. In the original post-hoc analysis undertaken by Savient that led to the current labeling, Savient analyzed a scenario in which uric acid levels drawn before an infusion would have been used for monitoring and decision making with the *next infusion* two weeks later. There is a practical rationale for this, as uric acid testing requires drawing blood and sending it to the laboratory, so results are unlikely to be available for several hours, or perhaps not until the next day, depending on where the laboratory is and how quickly the laboratory can process the samples. Thus, it is not unreasonable to imagine using the results obtained before one infusion to inform decision making on the next infusion.

145. Horizon took a different approach for the post-hoc analysis it presented in the ghostwritten article to further misrepresent and downplay the risks of Krystexxa. It revisited the clinical study data to purportedly "simulate" the effects of using uric acid levels drawn the day of an infusion to inform whether the infusion *that day* should be given or not. This would be expected to be more informative regarding the risk of infusion reaction than a level drawn two weeks prior, as immunity (and loss of effect leading to high uric acid) may have developed since the prior infusion. Indeed, the incidence of infusion reactions appeared to be lower than with the

Savient approach, and lower than what is stated in the label. However, the downside to measuring the uric acid the same day as an infusion is an important practical issue. As noted above, the results may take several hours to come back, or may not be available until the next day, causing long delays for the patient, as well as the physician and his/her staff, prior to the infusion. Horizon sought to make this approach seem more manageable in the article, and subsequently in its promotional material that followed, by suggesting the re-analysis could tell physicians what the infusion reaction risk would be if the uric acid level was drawn 1-2 days before the infusion. The introduction section of the article reads: "The purpose of this analysis was to quantify the reduction in IRs [infusion reactions] if pre-treatment sUA levels were checked 1-2 days before pegloticase infusions subsequent to the initial infusion".[24] This is not possible, and thus is misleading, because the analysis was unable to quantify the reduction in infusion reactions in this scenario – that is not how the study was designed or conducted. As a scientific article, one could forgive this claim as simply sloppy or imprecise language. However, as a promotional tool being ghostwritten by the marketing team of Horizon that is responsible for increasing drug revenues, this is clearly an attempt to make data sound more definitive and more informative than it really is. This theme is subsequently repeated in Horizon's promotional material which reads, "Close monitoring of sUA within 48 hours prior to the infusion can significantly reduce infusion reactions," and gives specific instructions to "Draw sUA level ~48 hours prior to infusion and use results to inform Monitoring Protocol" in order to achieve the 2% infusion reaction rate. Horizon's subsequent promotional material referenced the ghostwritten LaMoreaux article for validation of this misleading claim.

[24] LaMoreaux et al. *Use of Infusion Serum Uric Acid Levels as a Biomarker for Infusion Reaction Risk in Patients on Pegloticase*, RHEUMATOLOGY AND THERAPY 2019 at p. 301.

146. The article briefly attempts to address the inherent limitation that the conclusions drawn are based on sUA levels checked the day of the infusion, not "48 hours prior" to the infusion. It notes that "a limitation to this evaluation is that all sUA values in the study were drawn during the pegloticase infusions, yet in this analysis it was extrapolated that they were drawn 1-2 days before each infusion." This is misleading, also. There was no extrapolation in the analysis. Rather, the article makes the unfounded assertion that data exists to give physicians clear guidance on what percentage of patients will have infusion reactions if sUAs are checked within 1-2 days prior to an infusion and stopping rules are applied. But no such data exists. Again, this may be accepted as imprecise language in an ordinary scientific article, but since this particular article was ghostwritten by Horizon, and Horizon intended the article to pose as "independent" research, and intended to cite it in subsequent commercial promotional literature and communications with physicians to provide directive instructions to physicians and assuage their concerns with Krystexxa with a false assertion of lowered risk of infusion reactions, it is clear that the article was a tool for off-label promotion, and Horizon drafted it to knowingly mislead physicians by falsely downplaying risks to boost sales of the drug.

147. Of note, the ghostwritten article closes by describing uric acid monitoring as a "powerful tool" to inform physicians – that description is echoed in the title of Horizon's subsequent promotional literature, where Horizon claims that uric acid is a "powerful biomarker" to inform clinical practice. The overlapping messaging between the ghostwritten article and Horizon's subsequent sales literature was not a coincidence and reflected the direct involvement of the marketing team in the content of the "scientific" article, to facilitate off-label promotion and mislead physicians on the known risks of Krystexxa.

iii. Deceptive Promotional Materials (Misbranding and Off-Label Marketing in Horizon's Core Visual Aid Marketing Pamphlet)

148. After the ghostwritten article was published, Horizon turned to developing promotional material to be used by sales representatives in their deceptive communications with doctors. Horizon prepared a Core Visual Aid Pamphlet ("CVA") – a promotional document – which contains material that is misleading to physicians and inconsistent with product labeling: (a) it contains false safety data that the FDA rejected after deeming it improper to include with product labeling; (b) it contains misleading directives to prescribers to use serum uric acid monitoring in clinical care whose effectiveness has not been tested; (c) it falsely communicates a lower incidence of infusion reactions than the approved US PI will permit; (d) it includes misleading information about the efficacy of the drug and downplays risks of infusion reaction risks to drive increased prescriptions, sales and profits; (e) and it cites primarily to the ghostwritten article.

149. Specifically, the CVA contains numerous misrepresentations or conceals data that is inconsistent with labeling and deemed inappropriate by FDA.

150. The deception starts with the misleading Title of the CVA. It reads, "Serum Uric Acid (sUA): A Powerful Biomarker that Informs the Safety and Efficacy of KRYSTEXXA in Clinical Practice". The title implies that directive instruction (commonly found on a label approved by the FDA) will be provided to inform clinical use of the drug, while it conceals the fact that the data shown in the CVA is inconsistent with labeling and was deemed inappropriate for labeling by the FDA.

151. The Figure (on page 3 of the CVA) titled, "Incidence of Infusion Reactions Based on sUA Levels (Per 100 Infusions)" further misleads the reader. This Figure is misleading because this is the first time in the CVA that rates of infusion reactions are depicted, yet the

primary (on-label) data that 26% of patients had infusion reactions is omitted. Instead, this Figure displays a post-hoc analysis showing the rate of infusion reactions *per 100 infusions administered*, broken down by the uric acid level prior to the infusion. This figure is also misleading because:

- It provides infusion reaction rates that are ***dramatically*** lower than in product labeling (<1% or 5% in the per infusion analysis vs 26% in the subject incidence data included in the US PI), which misrepresents a lower risk of infusion reactions to prescribing physicians.
- It pools data from different treatment groups in the pivotal studies without making clear where the data is coming from.
- It does not acknowledge the post-hoc nature of the analysis; it does not state that these conclusions were not reached with a clinical study designed to make them.
- It does not acknowledge the inherent limitations of a per-100 infusion analysis (such as the bias towards a lower rate of adverse reactions in patients who tolerate the drug better and thus stay on the drug longer and receive more infusions).

152. The claim (on pages 4 and 5 of the CVA) which reads: "Close monitoring of sUA within 48 hours prior to the infusion can significantly reduce infusion reactions," is a known misrepresentation. This claim again relies on the article ghostwritten by Horizon's marketing department and containing data that the FDA had indicated was inappropriate for product labeling. It also provides an improper directive instruction to physicians that is based on a post-hoc analysis rather than prospective data; moreover, in the analysis this statement is based on, uric acid levels drawn the same day as the infusions, not "within 48 hours" of the next infusion. The statement implies far greater certainty than has been established in clinical studies to convince doctors to prescribe Krystexxa and thus puts patient safety at risk.

153. The Figure (on page 5 of the CVA) supporting this claim contains specific data that ***falsely reassures physicians about expected infusion reaction incidence when using a uric***

acid monitoring protocol, showing dramatically lower infusion reaction rates than in the FDA-approved product labeling. Based on a post-hoc analysis, Horizon claims these rates would have been observed in the pivotal studies if the drug had been stopped once loss of efficacy occurred. There is no way to know that is true. The Figure claims rates of infusion reactions in 2% or 8% of subjects (depending on which "stopping rules" were used), which is substantially lower than the 26% reported in the product's prescribing information. This is data the FDA specifically indicated was inappropriate for labeling and rejected in prior correspondence with Horizon. This Figure also never explicitly states that the 26% in the Figure refers to the percent of patients having infusion reactions in the clinical studies, thus obscuring the important information from the US PI. Moreover, senior management made the decision to include the 8% and 2% data (from the ghostwritten paper) in the CVA. Relator became aware of a meeting attended by Mr. Marcus and other staff including senior leadership at Horizon for commercial, medical affairs, and compliance. Mr. Marcus indicated that the meeting was attended by very senior leadership at Horizon for commercial, medical affairs, and compliance. The matter of including reference to these figures was clearly a known compliance risk, but as Marcus put it, "they have a lot more to gain" than he did, so Horizon was willing to take the risk.

154. The Table (on page 6 of the CVA): "Severity of Infusion Reactions in the Pivotal Clinical Trials" is also misleading. This Table reports the rates of mild, moderate, or severe infusion reactions in the pivotal clinical studies and, in smaller text below the main table, notes the "4 cases of severe infusion reactions identified by investigators were retrospectively reclassified as anaphylaxis by the FDA." This language diminishes the importance of these findings by implying that it was in some way questionable whether the infusion reactions classified as anaphylaxis by the FDA met a clear clinical standard of anaphylaxis. There is no

basis for making that suggestion. Rather, this statement is made to be consistent with a key internal Horizon talking point by the Marketing and Medical Affairs teams to diminish the perceived relevance of the anaphylaxis cases occurring in the clinical studies. Horizon worked to create the false impression that Krystexxa did not really pose the risk of life-threatening anaphylaxis when it did.

155. The Figure (on page 3 of the CVA) which reads, "sUA Levels Throughout the 6-Month Pivotal Clinical Trials" further misleads the reader. This Figure describes the group of subjects in the pivotal studies who did not meet the primary endpoint as "incomplete responders." The US PI refers only to subjects who met response criteria versus those who did not. The term "incomplete responders" ***overstates the efficacy***, as these are subjects who did not meet the criteria defining response, and which is also inconsistent with FDA approved labeling.

156. Overall, the claims, figures and tables in the CVA omit primary on-label data that 26% of patients who used Krystexxa suffered infusion reactions among other concerns; they suggest that an untested monitoring method can reduce the risks of Krystexxa to 8% or even 2%, a completely unverified false and fraudulent claim, which also disregards that infusion reactions, including anaphylaxis, can occur with the very first infusion of the drug, as was seen in 3% of patients in the clinical studies leading to approval (and reflected as such in product labeling); they imply that "anaphylaxis" reactions, the most dangerous life-threatening reactions associated with Krystexxa, were overstated or misclassified and should not be taken seriously. The uric acid stopping rules cannot prevent infusion reactions or anaphylaxis with the first infusion. The rate Horizon reports of 2% incidence of infusion reactions with the stopping rules ignores the risk of reactions with the first infusion, where stopping rules don't apply, further showing the 2% figure is misleading. In sum, the figures and tables in the CVA convey false or misleading

information, downplay the risks, propose untested protocols and overstate the efficacy of Krystexxa, and should never have been included in the CVA.

iv. Sham Safety Boards to Boost Sales

157. To further increase sales and deceptively downplay the risks of Krystexxa, Horizon funded 12-15 commercial advisory "safety board" meetings in one year to communicate the same off-label data to doctors and prescribers. These "safety boards" were gatherings of physicians – prescribers or potential prescribers of Krystexxa – invited to meet Horizon marketing staff. The "safety boards" would include a presentation of data by Horizon's Director of Medical Affairs Brian LaMoreaux, another Horizon medical team member (e.g. a field-based medical "liaison"), or an external physician (such as Drs. Botson or Peterson), along with participation of marketing staff. These advisory boards were ostensibly conducted to seek "feedback" about Krystexxa from the invited participants. However, these meetings were not legitimately conducted to obtain feedback or disseminate clinical information or new research. Rather, these "safety boards" were intended to market and promote Krystexxa by downplaying the risks of Krystexxa in order to drive up sales. These so-called "safety boards" presented Horizon's post-hoc data analyses to attendees; rather than discussing safety issues, they served as a platform for disseminating over and over again the data rejected by the FDA for labeling (off-label misinformation) in order to boost sales; and they were used to improperly reassure prescribers of a safety profile that contradicted FDA guidance. The data included in the CVA and the ghostwritten article played center stage at these "safety board" meetings to mislead doctors about Krystexxa. Since the same information was presented at these meetings, they lacked educational value and Horizon received little, if any, feedback from the attendees.

158. Participants at these meetings, including Drs. Botson and Peterson, were paid for their participation in addition to having travel and meal expenses covered or reimbursed. It is common for drug companies to set up advisory boards on a limited basis, for commercial or medical/research staff to get feedback from physicians or other healthcare providers on select topics. However, as a general rule, in planning these events, it is required that the feedback be truly needed, not obtainable via other mechanisms, and not already obtained via prior meetings; if the objective of these boards is data or messaging communication from the drug company to physicians – which is precisely what Horizon intended – it is unacceptable and is off-label promotion. The safety boards for Krystexxa had a clear objective: to communicate off-label "safety" data – not receive feedback. They were intended to be and actually served as a marketing tool that presented misleading information to persuade prescribers to use Krystexxa more often and drive sales of the drug. As a result of these meetings, Horizon increased the sales of Krystexxa.

159. These were commercial advisory boards during which medical staff would participate to present the data. Medical staff were present and accompanied by Horizon sales and marketing staff. Having a limited number of these events (e.g. one per year on a single topic) to get feedback on data communication would be reasonable. Having repeated advisory boards – 12 to 15 – with similar types of physicians (i.e. community practice rheumatologists) addressing the same topics was clearly intended to disseminate information, not to receive feedback from advisors. In this case, these sham safety boards were actually commercial advisory boards, disseminating off-label information, misleading physicians and successfully boosting sales.

v. Kickback Payments to the Top Prescribers of Krystexxa

160. Last, but not least, Horizon paid kickbacks to high prescribers of Krystexxa, namely, Drs. John Botson of OPA and Jeff Peterson of WWM, who are responsible for approximately 20-25% of Krystexxa sales nationwide, according to Michael Nagro, Horizon's Senior Director of Marketing. These two doctors had access to Horizon's top leadership, including Chief Commercial Officer Vikram Karnani, who told Horizon employees "keep them happy," and "make them feel important," according to Horizon's Vice President of the Therapeutic Area and Head of Rheumatology – Clinical Development, Dr. Paul Peloso. Karnani was directly involved with marketing and Drs. Botson and Peterson would complain to him directly about anything they were not happy with. Staying in their good graces incentivized Drs. Botson and Peterson to continue prescribing Krystexxa at unusually high rates. But for the prescriptions these doctors wrote for Krystexxa, Horizon would not have paid or compensated them with amounts exceeding fair market value for their levels of experience.

161. Despite Drs. Botson and Peterson lacking the required experience and credentials – they were not researchers, had no FDA experience, lacked any understanding of FDA procedures or protocols – Horizon paid them exorbitant fees (above fair market value) for consulting, honoraria, research and regulatory advice, and hired them for speaking events for the marketing team. Horizon paid these doctors exorbitant consulting fees at the same time that they tried to prevent them from speaking directly with FDA or meeting with FDA officials because they lacked the required experience and expertise to do so. For example, Drs. Botson and Peterson were both involved in giving Horizon feedback on the clinical study (MIRROR randomized trial) on which Horizon was seeking FDA feedback, and Dr. Botson was invited to live planning meetings with Horizon's Shao-Lee Lin (Executive Vice President, Research and Development, and Chief Scientific Officer), Jeff Kent (Executive Vice President, Medical

Affairs, and Outcomes Research), Paul Peloso (Vice President of Clinical Development), and even the CEO Tim Walbert, as Dr. Botson had been invited to attend a face-to-face meeting with FDA. Relator had direct knowledge of email exchanges and phone calls with Dr. Botson and Peterson to address their comments on the study plan. They were both quite opinionated and at times inflammatory during correspondence and conversations with them, arguing that Horizon should not need a randomized, controlled study because the FDA should "just believe us" that we could improve response rates to Krystexxa with the addition of an immunomodulator (methotrexate) to the treatment regimen; they also argued that physicians could start using methotrexate along with Krystexxa without a label change, and that the "word would get out" that response rates were better when methotrexate was added. The need to confirm the safety and efficacy of this approach, and the FDA requirement for rigorous data for a label update, were lost on them. But because Horizon had to "keep them happy," repetitive correspondence and meetings with them were undertaken to reiterate that a robust study was required to enable an update to the label, and to confirm their anecdotal observations from their own practices. Shortly before the FDA meeting, Relator learned that Dr. Botson had been inflammatory in a meeting with Shao-Lee Lin, Jeff Kent, and Tim Walbert and that Mr. Walbert told Mr. Peloso to "get Botson in line." Based on that same meeting, Shao-Lee Lin told Paul Peloso that it would be best if Dr. Botson did not speak at the FDA meeting. Dr. Botson still made the trip to Washington for the FDA face-to-face meeting, where ultimately he did not speak. Horizon clearly knew Drs. Botson and Dr. Peterson did not justify the lucrative payments they were receiving.

162. Drs. Botson and Peterson were given lucrative compensation as promotional speakers and consultants; they were allowed to give input on clinical study design despite

lacking the required experience and expertise; they were tasked to assist with preparing briefing documents and even a slide deck to present to the FDA on a MIRROR Randomized-Controlled Trial for Krystexxa and even attend an FDA meeting (even though they lacked knowledge and experience dealing with FDA); they were enlisted to participate in preparing promotional materials; and they received the highest rate for consulting ($500/hour) even though they lacked any prior consulting expertise. Horizon's Paul Peloso, Vice President of Clinical Development, in the Therapeutic Area and Head for Rheumatology, even approved funding for a research coordinator for Dr. Botson so he could participate in the MIRROR study, above and beyond the routine payment for study activities (study visits, completion of study assessments, etc.) that were normally reimbursed as part of study conduct.

163. According to data generated by the requirements of the Federal Physician Sunshine Act, 42 U.S.C. § 1320a-7h, Drs. Botson and Peterson have been paid over $252,000 and $188,000, respectively, by Horizon, for consulting fees, honoraria and travel and lodging, in 2019 alone.[25] Horizon payments to Drs. Botson and Peterson have increased steadily throughout their association. Prior to Horizon acquiring the rights to Krystexxa, Horizon did not pay Drs. Botson or Peterson any fees whatsoever. In 2016, the first year that Horizon owned the rights to Krystexxa, Horizon paid Drs. Botson and Peterson $23,860 and $20,515, respectively. The next year, Horizon more than doubled these amounts: in 2017, Horizon paid Drs. Botson and Peterson $51,197 and $50,292, respectively. The next year Horizon doubled its payments to Dr. Botson and increased payments to Dr. Peterson by 50%: in 2018, Horizon paid Drs. Botson and Peterson $96,294 and $74,383, respectively. As of 2018, Horizon paid Drs. Botson and Peterson more than all other companies making payments to them, combined. In 2019, out of the 15,372

[25] *See* https://openpaymentsdata.cms.gov/company/100000131389 for data concerning Horizon payments to Drs. Botson and Peterson from 2016-2019.

doctors that Horizon makes payments to, Drs. Botson and Peterson rank as the 2nd and 4th highest paid by Horizon. Again, these amounts are for general payments only; they do not include amounts paid to Drs. Botson and Peterson for research or associated research funding, amounts which are not publicly available on the CMS website. No general payment data is available for 2020 yet, but upon information and belief, Relator believes that these payments from Horizon to Drs. Botson and Peterson have increased steadily over the years. Moreover, according to CMS's Open Payments Data, all of these payments are made by Horizon Therapeutics PLC (formerly known as Horizon Pharma PLC).

164. Such remunerations are kickbacks when paid to induce or reward physicians for writing prescriptions. Kickbacks increase Government-funded health benefit program expenses by inducing medically unnecessary overutilization of prescription drugs and excessive reimbursements. Kickbacks also reduce a patient's healthcare choices, as physicians may prescribe drug products based on the physician's own financial interests rather than according to the patient's medical needs. Payments to Drs. Botson and Peterson were made to influence their prescriptions of Krystexxa – either to maintain or increase their use of the drug and influence others to do so. Horizon achieved millions in Krystexxa sales as a result of payments and remuneration paid to Drs. Botson and Peterson in connection with their consulting arrangements. Thus, every single claim submitted by Drs. Botson and Peterson during the Covered Period was rendered false.

165. To further entangle Drs. Botson and Peterson, Horizon even used their practice offices as clinical study recruiting sites and gave them high levels of support for the study despite a lack of infrastructure or expertise in such studies. This was intended to reward them for the roles as prescribers and speakers on behalf of Horizon, and to bolster their research credentials to

make them more credible as speakers. Even though their offices were located in Alaska and Eastern Washington state, Horizon used them as sites to recruit subjects for a MIRROR Open-label study and a MIRROR Randomized-Controlled Trial despite the logistical difficulties of using patients from such remote distances. These studies involved more than 100 patients. Horizon established plans to pay for subjects in Alaska to be flown to Dr. Botson's site in order to allow his office's participation as a study site. Paul Peloso also approved a request for Horizon to pay for a study coordinator to support Dr. Botson's office as a study site, an unusual arrangement as this was support beyond the routine payments for research participation that sites would receive. Horizon was prepared to incur exorbitant costs for transportation, food and overnight lodging – expenses usually avoided in clinical trials. Also, because the use of Krystexxa involved blood draws the day prior to dosing and in between dosing for efficacy assessments at some study time points, patients would need frequent flights to the study site including overnight stays to accommodate the required study visits. Horizon agreed to pay, and paid, for all of this.

166. Drs. Botson and Peterson were even given controlling roles in a three person "scientific advisory group" along with Horizon's Vice President, Dr. Peloso, for purposes of consulting on one of the Krystexxa clinical studies (the MIRROR Open-Label Study; NCT03635957). Mid-way through the study, these doctors ordered a change in protocol when the desired results were not being achieved, and recommended that Horizon triple the steroid dose used with the drug to reduce the risk of infusion reactions and attempt to increase the response rate with Krystexxa. The high doses of steroids they recommended can put patients at risk when used over an extended period, such as over the one-year duration of study that was planned. In addition, a change of protocol in the middle of a study can invalidate the results, thus

undermining the study as a whole. Evidently, these doctors were so economically invested in the success of these clinical trials that they were willing to risk the safety of the participants in order to achieve the desired results.

167. Furthermore, Drs. Botson's and Dr. Peterson's judgment was being influenced by the kickbacks they received from Horizon. For example, in the first, small open-label MIRROR study, there was a participant who had a loss of efficacy (sUA elevated x2) and thus needed to stop receiving the drug per the study protocol. However, Dr. Peterson wanted to continue to treat the patient with commercial product, despite sUA elevation. He had the patient return and receive an infusion, resulting in a severe infusion reaction (diffuse hives, nausea, etc.). He declined to describe the reaction as anaphylaxis, although the criteria seemed to have been met. This did not get reported as a adverse event in the study, but Relator ensured this was reported through the post-marketing safety reporting mechanism in place at Horizon. The experience reveals how much Drs. Botson and Peterson were influenced by the kickbacks and achieving favorable results at the risk of patient safety.

168. Ultimately, Dr. Botson's institutional review board concluded that he was too "conflicted" to participate in any review of raw data for these clinical trials due to his significant level of compensation from Horizon and ordered he be removed from data review. Horizon anticipated that Dr. Peterson would be assessed as having a similar level of conflict of interest, with the implication that it would be inappropriate to have either physician participate in the "scientific advisory group."

169. If Drs. Botson and Peterson are presumed to be responsible for approximately 20% of Krystexxa sales nationwide, then their prescriptions alone accounted for $50-62.5 million of Horizon's revenue in 2018 (via 200 to 250 patients). Since these doctors were paid hundreds

of thousands of dollars in kickbacks, all of the claims submitted by them and their practices for Krystexxa are tainted and subject to forfeiture pursuant to the federal healthcare Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b). Knowingly paying kickbacks to physicians to induce them to prescribe a prescription drug on-label or off-label (or to influence physician prescriptions) for individuals who seek reimbursement for the drug from a government healthcare program or causing others to do so, while certifying compliance with the federal healthcare AKS (or while causing another to so certify), or billing the Government as if in compliance with these laws, violates the FCA and similar state False Claims Acts.

170. Horizon is intimately aware of the prohibition on "the payment or receipt of kickbacks, bribes, or other remuneration to induce the purchase or recommendation of healthcare products or services or reward past purchases or recommendations."[26] Not surprisingly, Horizon has warned its shareholders that some of "its business activities may be subject to challenge under one or more laws."[27]

vi. Compensation for Off-Label Marketing

171. Horizon rewards its sales representatives in the form of bonuses based on the volume of sales they attain, regardless of whether the sales were ill-gotten with off-label or misleading communications. Because off-label or misleading communications have the potential to increase the size of the target patient base and thus sales volume, Horizon is knowingly incentivizing off-label marketing.

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[26] *See* 2018 Horizon Form 10-K at 27.

[27] *See* 2018 Horizon Form 10-K at 30 ("Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities in the United States could be subject to challenge under one or more of such laws."). "In November 2015, [Horizon] received a subpoena from the U.S. Attorney's Office for the Southern District of New York requesting documents and information related to [its] patient access programs and other aspects of [its] marketing and commercialization activities." *Id.* at 39.

VII. ACTIONABLE CONDUCT BY HORIZON UNDER THE FALSE CLAIMS ACT

A. Applicable Law

i. False Claims Act

172. This is an action to recover damages and civil penalties on behalf of the United States and Relator arising from the false or fraudulent statements, claims and acts by Horizon made in violation of the False Claims Act, 31 U.S.C. §§ 3729-3732.

173. The FCA provides that any person who:

a. knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;

b. knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

c. conspires to defraud the Government by committing a violation of the FCA;

d. knowingly makes, uses, or causes to be made or used, a false record or statement to conceal material to an obligation to pay or transmit money or property to the Government

is liable to the Government for a civil penalty of not less than $11,181 and up to $22,363 for each such claim, plus three times the amount of damages sustained by the Government because of the false or fraudulent claim.

174. The FCA allows any persons having knowledge of a false or fraudulent claim against the Government to bring an action in federal district court for themselves and for the United States Government and to share in any recovery as authorized by 31 U.S.C. §3730.

175. Based on these provisions, Relator, on behalf of the United States Government and the States of California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, the Commonwealth of Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New

Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, the Commonwealth of Virginia, Washington and the Commonwealth of Puerto Rico (collectively the "States") seeks through this action to recover damages and civil penalties arising from Horizon's causation of the submission of false claims to the federal and state governments. In this case, such claims were submitted to the federal and state governments for payment for Horizon's drug, Krystexxa. Relator alleges that the United States and the states have suffered significant damages as a result of false claims for payment for Krystexxa.

176. There are no bars to recovery under 31 U.S.C. §3730(e), and, or in the alternative, Relator is an original source as defined therein. Relator has direct and independent knowledge of the information on which the allegations are based. As required pursuant to 31 U.S.C. §3730(b) and (e), Relator has voluntarily provided information, oral and/or written, and has sent disclosure statement(s) of all material evidence, information and documents related to this Complaint, both before and contemporaneously with filing, to the Attorney General of the United States, the United States Attorney for the Southern District of New York, and the Attorneys General of the various states, commonwealths, and the District of Columbia.

B. Defendants' Violations of the FCA

i. Horizon's Off-Label Marketing Schemes Violated the FCA

177. Because of the illegal acts described above, Horizon has made or will make millions of dollars in sales of Krystexxa to Medicaid, Medicare, CHAMPUS/TRICARE, CHAMPVA, FEHBP, and other federal healthcare program patients. Moreover, Horizon violated the FDCA by distributing Krystexxa as a misbranded drug. Horizon illegally misbranded Krystexxa because the drug labeling and promotional material were false or misleading, its labeling did not bear adequate directions for use, and/or its labeling did not bear adequate warnings against unsafe dosage or methods of administration or application in accordance with

the FDA approved US PI. Horizon's conduct also violated federal laws prohibiting a manufacturer from promoting its drugs with misleading off-label false statements. These claims were not eligible for payment by Medicaid, Medicare Part B, or Medicare Part D, CHAMPUS/TRICARE, CHAMPVA, FEHBP, or other federal healthcare programs because these off-label promotions resulted in prescriptions that were neither "reasonable and necessary," nor "medically accepted."

178. Horizon violated the Anti-Kickback Statute by providing the kickbacks to doctors in the form of consulting fees at amounts that were greater than fair market value, in addition to paid commercial speaker fees and payment for participation in clinical trial research. The sheer amount paid to the highest prescribers of Krystexxa and the admission of Horizon's officers to keep such prescribers "happy," point to the conclusion that these payments were mere incentives or rewards for prescribing Krystexxa. Drs. Botson and Peterson wrote millions of dollars of Krystexxa prescriptions as a result of the kickbacks they received and funneled payment through their practices at OPA and WWM.

179. Horizon knew that its false marketing materials, false and misleading off-label representations and kickbacks would induce doctors, especially Drs. Botson and Peterson, to write prescriptions that were not "reasonable and necessary," or "medically accepted," or prescriptions tainted by kickbacks. Horizon also knew that its false marketing, fraudulent misrepresentations and kickbacks would cause physicians to submit claims for fraudulent reimbursement by federal and state healthcare programs under these circumstances. Drs. Botson and Peterson submitted such claims and continue to do so.

180. Horizon's fraudulent scheme to aggressively and illegally market its drugs and misbrand Krystexxa and to integrate various forms of illegal kickbacks into its off-label sales

campaigns led to increased prescriptions for its drugs. Prescriptions for Krystexxa for which Medicaid, Medicare Part B, Medicare Part D, CHAMPUS/TRICARE, CHAMPVA, FEHBP, and other federal healthcare programs paid were a direct result of these illegal sales campaigns. Thus, these Medicaid, Medicare Part B, Medicare Part D, CHAMPUS/TRICARE, CHAMPVA, FEHBP, and other federal healthcare program claims for off-label prescriptions are tainted by the associated illegal kickbacks, as well as by Horizon's off-label marketing statements for Krystexxa. Horizon's scheme violated the Anti-Kickback Statute and the FDA's prohibitions on off-label promotion, and therefore caused false claims to be submitted by physicians in violation of the FCA. By orchestrating and taking part in this fraudulent scheme, Horizon, Drs. Botson and Peterson, and their practices, OP and WWM, repeatedly and with continued knowledge violated the False Claims Act, 31 U.S.C. § 3729(a).

181. The ultimate submission by doctors of false pharmaceutical claims to Medicare, the state Medicaid programs, CHAMPUS/TRICARE, CHAMPVA, and FEHBP was a foreseeable factor in the Government's loss, and a consequence of the scheme. Given the structure of the health care systems, Horizon's false statements, representations, and records made, used, or caused to be made or used had the potential to influence the Government's payment decision. Consequently, the States and the United States Government have suffered substantial damages.

182. Because of the illegal acts described above, Horizon has made or will make millions of dollars in sales of Krystexxa to patients it would not otherwise achieve; and Drs. Botson and Peterson, and OPA and WWM will earn hundreds of thousands of dollars in rewards for writing prescriptions that were neither "reasonable and necessary," nor "medically accepted." The ultimate submission by physicians and pharmacists of false claims to the state Medicaid

programs, Medicare, CHAMPUS/TRICARE, CHAMPVA, FEHBP, and other federal healthcare programs was a foreseeable factor in the government's loss, and a consequence of the scheme. Consequently, the States and the United States Government have suffered substantial damages.

ii. Horizon Conspired with Physicians to Defraud the Government in Violation of the FCA

183. Horizon conspired with physicians such as Drs. Botson and Peterson to promote Krystexxa with misleading off-label statements in violation of the FCA and to pay kickbacks to physicians in violation of the Anti-Kickback Statute in order to induce physicians to prescribe high volumes of Krystexxa. As Horizon knew would be the case, Horizon's actions resulted in the submission to state Medicaid programs, Medicare, CHAMPUS/TRICARE, CHAMPVA, FEHBP, and other federal healthcare programs of false and/or fraudulent claims for reimbursement for Krystexxa, violating the FCA, 31 U.S.C. § 3729(a)

184. Given the structure of the health care systems, false statements, representations, and records made, used, or caused to made or used, by Horizon had the potential to influence the government's payment decision.

185. Because of the illegal acts described above, Horizon has made or will make millions of dollars in sales of Krystexxa to patients it would not otherwise achieve. The ultimate submission by physicians and pharmacists of false claims to the state Medicaid programs, Medicare, CHAMPUS/TRICARE, CHAMPVA, FEHBP, and other federal healthcare programs was a foreseeable factor in the government's loss, and a consequence of the scheme. Consequently, the States and the United States Government have suffered substantial damages.

iii. Damages

186. Krystexxa prescriptions that resulted from false certification would not have been reimbursed by Medicare Part B, Medicare Part D, the state Medicaid programs,

CHAMPUS/TRICARE, CHAMPVA, FEHBP, ADIS Drug Assistance Programs ("ADAPs"), and other federal healthcare programs, had the U.S. Government or the States known the circumstances under which the requests for reimbursement were submitted and the laws violated by Horizon in order to increase sales and claim reimbursements. Consequently, the States and the United States Government have suffered substantial damages.

187. Generally, customers are willing to pay higher prices for high-quality drugs versus lower-quality drugs. Because Horizon touted Krystexxa as a drug with fewer health risks, representations which were off-label, the price of Krystexxa was inflated. By making the drug seem less dangerous and more efficacious, more physicians would move to use it sooner, rather than waiting longer for oral drugs to work. Had Horizon marketed Krystexxa only according to the label approved by the FDA, Krystexxa would have fetched a lower price on the market and achieved lower annual sales.

VIII. CAUSES OF ACTION

Count 1 –
False Claims
(31 U.S.C. § 3729(a)(1)(A)

188. Relator realleges and hereby incorporates by reference each and every allegation contained in the preceding paragraphs of this Complaint.

189. By virtue of the acts alleged herein, Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A).

190. As a result of Horizon's off-label marketing scheme and kickbacks to physicians to induce them to prescribe Krystexxa, all of the claims that Horizon caused physicians and third-party payers to submit to the state Medicaid programs, Medicare, CHAMPUS/TRICARE,

CHAMPVA, FEHBP and other federal healthcare programs are false or fraudulent. Horizon knowingly caused such false or fraudulent claims to be presented for payment or approval, in violation of 31 U.S.C. § 3729(a)(l).

191. The United States Government paid the false and/or fraudulent claims.

192. By virtue of the false or fraudulent claims that Horizon knowingly caused to be presented, the United States Government has suffered substantial monetary damages.

193. As a result of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial, and the United States is entitled to penalties of at least $11,181 and up to $22,363 for each and every violation of 31 U.S.C. § 3729(a) arising from Defendants' unlawful conduct as described herein.

Count 2 -
False Records or Statements
(31 U.S.C. § 3729(a)(1)(B))

189. Relator realleges and hereby incorporates by reference each and every allegation contained in the preceding paragraphs of this Complaint.

190. By virtue of the acts alleged herein, Defendants knowingly made, used, or caused to be made or used, false records or statements – *i.e.*, the false certifications and representations made or caused to be made by Defendants – material to false or fraudulent claims in violation of 31 U.S.C. § 3729(a)(1)(B).

191. By submitting claims for payment and retaining improperly obtained payments, Defendants expressly and impliedly, if falsely, certified to their compliance with the relevant Government and CMS regulations authorizing such payments.

192. Horizon knowingly made or used, or caused to be made or used, false records or statements, and omitted material facts (a) to get false or fraudulent claims paid or approved by

the Government, or (b) that were material to false or fraudulent claims, in violation of 31 U.S.C. § 3729(a). The false records or statements included, but were not limited to, the false or misleading materials and other statements provided to physicians, and the federal and state governments to induce physicians to prescribe high volumes of Krystexxa, and the physicians' and third-party payers' false certifications and representation of full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Anti-Kickback Statute. By submitting claims for payment and retaining improperly obtained payments, Defendants expressly and impliedly, if falsely, certified their compliance with the relevant Government and CMS regulations authorizing such payments. Each prescription that was written as a result of the Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And each claim for reimbursement for such prescriptions submitted to a federal health insurance program represents a false and/or fraudulent claim for payment.

193. By virtue of the false records or statements that Horizon made or used, the United States Government has suffered substantial monetary damages.

194. As a result of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial, and the United States is entitled to at least $11,181 and up to $22,363 for each and every violation of 31 U.S.C. § 3729 arising from Defendants' unlawful conduct as described herein.

Count 3
False Claims Conspiracy
(31 U.S.C. § 3729(a))

195. Relator realleges and hereby incorporates by reference each and every allegation contained in the preceding paragraphs of this Complaint.

196. Defendants conspired to promote Krystexxa with misleading off-label statements in violation of the FCA and to pay kickbacks to physicians in violation of the Anti-Kickback Statute to induce physicians to prescribe high volumes of Krystexxa, thereby causing all of the physicians' and third-party payers' claims to the state Medicaid programs, Medicare, CHAMPUS/TRICARE, CHAMPVA, FEHBP, and other federal healthcare programs to be false or fraudulent. Accordingly, Horizon conspired to defraud the Government by (a) getting false or fraudulent claims allowed or paid, or (b) committing a violation of the FCA, in violation of 31 U.S.C. § 3729(a). By virtue of the false or fraudulent claims submitted, paid, or approved as a result of Defendant's conspiracy to defraud the Government, the United States has suffered substantial monetary damages.

Count 4 –
Reverse False Claims
(31 U.S.C. § 3729(a)(1)(G))

197. Relator realleges and hereby incorporates by reference each and every allegation contained in the preceding paragraphs of this Complaint.

198. By virtue of the acts alleged herein, Defendants knowingly made, used, or caused to be made or used, false records or false statements that are material to an obligation to pay, transmit, or return money to the Government.

199. As a result of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial, and the United States is entitled to at least $11,181 and up to $22,363 for each and every violation of 31 U.S.C. §3729(a) arising from Defendants' unlawful conduct as described herein.

Count 5 –
Violations of the Anti-Kickback Statute
(42 U.S.C. § 1320a-7b, *et seq.*)

200. Relator realleges and hereby incorporates by reference each and every allegation contained in the preceding paragraphs of this Complaint.

201. As more particularly set forth in the foregoing paragraphs, Defendant Drs. Botson, Peterson, OPA and WWM, and their professional employees solicited and accepted kickbacks from Horizon. These kickbacks took the form of lavish consulting fees, advisory board meals, research payments, travel expenses, and events offered to and accepted by Defendants. For example, Horizon paid for Drs. Botson and/or Peterson to fly to Madrid, Spain to present Krystexxa data at the Annual European Conference of Rheumatology (EULAR) and paid for fancy dinners at that conference.

202. As a result of these unlawful kickbacks, Relator directly observed Defendants elect to use Krystexxa, despite the existence of other, less expensive, viable alternatives. Relator also observed these kickbacks result in conflicts of interest concerning ongoing clinical studies that placed the health and safety of the participants at risk.

203. This behavior caused the Government to pay more for services rendered than was medically necessary, in violation of the Anti-Kickback Statute.

204. The Anti-Kickback Statute contains statutory exceptions and regulatory "safe harbors" excluding certain types of conduct from liability. *See* 42 U.S.C. § 1320a-7(b)(3) and 42 C.F.R. § 1001.952. None of these statutory exceptions or regulatory safe harbors apply to in this matter.

Count 6
California False Claims Act
(Cal. Gov't Code § 12650, *et seq.*)

205. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

206. This is a *qui tam* action brought by Relator and the State of California to recover treble damages and civil penalties under the California False Claims Act, Cal. Gov't. Code § 12650, *et seq.*

207. Cal. Gov't Code§ 12651(a) provides liability for any person who-

(a) knowingly presents, or causes to be presented, to an officer or employee of the state or of any political division thereof, a false claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision;

(c) conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision;

(d) knowingly makes, uses, or causes to made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision;

(e) is a beneficiary of an inadvertent submission of a false claim to the state or a political subdivision, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

208. In addition, the payment or receipt of bribes or kickbacks is prohibited under Cal. Bus. & Prof. Code §§ 650 and 650.1, and is also specifically prohibited in treatment of Medi-Cal patients pursuant to Cal. Welf. & Inst. Code §14107.2.

209. Defendants knowingly violated Cal. Gov't Code § 12651(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of California from at least January 2010 to the present by violating Cal. Bus. & Prof. Code§§ 650-650.1 and Cal. Welf, & Inst. Code §14107.2 and the Federal Anti-Kickback Act, as described herein.

210. As a result of Horizon's off-label marketing and kickback schemes, all of the claims that Horizon knowingly caused physicians and pharmacists to knowingly submit to the California Medicaid program are false or fraudulent. Further, Horizon knowingly caused physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Anti-Kickback Statute and the California Anti-Kickback Statutes (Cal. Bus. & Prof. Code§§ 650-650.1 and Cal. Welf. & Inst. Code §14107.2). Compliance with federal and state laws and regulations was a condition of payment.

211. The State of California, by and through the California Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

212. Given the structure of the health care systems, the false statements, representations, and records made by Horizon had the potential to influence the State of California's payment decision.

213. The ultimate submission by physicians, pharmacists, and third-party payers of false and/or fraudulent claims to the state Medicaid program was a foreseeable factor in the State of California's loss, and a consequence of the scheme.

214. As a result of Defendants' violations of Cal. Gov't Code §12651(a), the State of California has been damaged.

215. There are no bars to recovery under Cal. Gov't Code § 12652(d)(3), and, or in the alternative, Relator is an original source as defined therein. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Cal. Gov't Code § 12652(c) on behalf of herself and the State of California.

216. This Court is requested to accept pendent jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of California in the operation of its Medicaid program.

217. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF CALIFORNIA:

- Three times the amount of actual damages that the State of California has sustained as a result of Defendants' fraudulent and illegal practices;
- A civil penalty of not less than $11,463 and not more than $23,331 for each false claim that Defendants presented or caused to be presented to the State of California;
- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATOR:

- The maximum amount allowed pursuant to Cal. Gov't Code § 12652 and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relator incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

Count 7
California Insurance Fraud Prevention Act
(Cal Ins. Code §§ 1871.1, *et seq.*)

218. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint

219. This is a claim for treble damages and penalties under the CIFPA.

220. Pursuant to Cal. Ins. Code § 1871.4(a), it is unlawful to:

> (1) Make or cause to be made a knowingly false or fraudulent material statement or material representation for the purpose of obtaining or denying any compensation, as defined in Section 3207 of the Labor Code.
>
> (2) Present or cause to be presented a knowingly false or fraudulent written or oral material statement in support of, or in opposition to, a claim for compensation for the purpose of obtaining or denying any compensation, as defined in Section 3207 of the Labor Code.
>
> (3) Knowingly assist, abet, conspire with, or solicit a person in an unlawful act under this section.
>
> (4) Make or cause to be made a knowingly false or fraudulent statement with regard to entitlement to benefits with the intent to discourage an injured worker from claiming benefits or pursuing a claim. For the purposes of this subdivision, "statement" includes, but is not limited to, a notice, proof of injury, bill for services, payment for services, hospital or doctor records, X–ray, test results, medical–legal expense as defined in Section 4620 of the Labor Code, other evidence of loss, injury, or expense, or payment.
>
> (5) Make or cause to be made a knowingly false or fraudulent material statement or material representation for the purpose of obtaining or denying any of the benefits or reimbursement provided in the Return–to–Work Program established under Section 139.48 of the Labor Code.
>
> (6) Make or cause to be made a knowingly false or fraudulent material statement or material representation for the purpose of discouraging an employer from claiming any of the benefits or reimbursement provided in the Return–to–Work Program established under Section 139.48 of the Labor Code.

221. By virtue of the acts described above, Defendants knowingly utilized a scheme by which it presented, or caused to be presented, false or fraudulent claims to private insurers in California, or for patients in California that those insurers covered (i.e., patients who hold private

insurance contracts and against whom Horizon could file claims for payment or approval) in violation of each patient's private health insurance contract.

222. By virtue of the acts described above, Defendants knowingly made, used or caused to be made or used false records and statements and omitted material facts to induce the private insurers in California, or for patients in California covered by those insurers, to approve or pay such false and fraudulent claims.

223. By virtue of the acts described above, Defendants conspired to violate the CIFPA and each patient's private health insurance contract.

224. The private insurers in California, or those insurers that covered patients in California, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by Horizon, paid and continue to pay the claims that are non-payable as a result of Horizon's illegal conduct.

225. Defendant knowingly submitted and/or caused to be made or used false records or false statements in order to avoid or decrease its obligation to return overpayments to these private insurance companies.

226. By reason of Defendants' acts, these private insurance companies have been damaged, and continue to be damaged, in a substantial amount to be determined at trial.

227. Each claim for reimbursement that was a result of Horizon's scheme represents a false or fraudulent record or statement and a false or fraudulent claim for payment.

228. The State of California is entitled to the maximum penalty of $150,000 per violation, plus an assessment of three times the amount of each false or fraudulent claim for compensation made, used, presented or caused to be made, used, or presented by Defendants.

Count 8
Colorado Medicaid False Claims Act
(C.R.S.A. § 25.5-4-304, *et seq.*)

229. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

230. This is a *qui tam* action brought by Relator on behalf of the State of Colorado to recover treble damages and civil penalties under the Colorado Medicaid False Claims Act, C.R.S.A. § 25.5-4-304, *et seq.*

231. Colorado's Medicaid False Claims Act, C.R.S.A. § 25.5-4-305, provides for liability for any person who

> (a) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (b) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim;
>
> (c) Has possession, custody, or control of property or money used, or to be used, by the state in connection with the "Colorado Medical Assistance Act" and knowingly delivers, or causes to be delivered, less than all of the money or property;
>
> (d) Authorizes the making or delivery of a document certifying receipt of property used, or to be used, by the state in connection with the "Colorado Medical Assistance Act" and, intending to defraud the state, makes or delivers the receipt without completely knowing that the information on the receipt is true;
>
> (e) Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the state in connection with the "Colorado Medical Assistance Act" who lawfully may not sell or pledge the property;
>
> (f) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state in connection with the "Colorado Medical Assistance Act", or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state in connection with the "Colorado Medical Assistance Act";
>
> (g) Conspires to commit a violation of paragraphs (a) to (f) of this subsection (1).

232. Defendants violated the Colorado Medicaid False Claims Act and knowingly caused false claims to be made, used and presented to the State of Colorado by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

233. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Colorado in connection with Defendants' conduct. Compliance with applicable Colorado statutes was also a condition of payment of claims submitted to the State of Colorado.

234. Had the State of Colorado known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

235. As a result of Defendants' violations of the Colorado Medicaid False Claims Act, the State of Colorado has been damaged in an amount far in excess of millions of dollars exclusive of interest.

236. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Colorado Medicaid False Claims Act on behalf of himself and the State of Colorado.

237. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Colorado in the operation of its Medicaid program

238. WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendant

To the STATE OF COLORADO:

- Three times the amount of actual damages which the State of Colorado has sustained as a result of Defendants' conduct;
- A civil penalty of not less than $11,463 and not more than $23,331 for each false claim which Defendants caused to be presented to the State of Colorado, except that this upper limit on liability is subject to an automatic adjustment in accordance with the federal Civil Penalties Inflation Adjustment Act of 1990 ("CPIAA");
- Pre- and post-judgment interest; and
- All costs incurred in bringing this action.

To RELATOR:

- The maximum amount allowed pursuant to Colorado Medicaid False Claims Act and/or any other applicable provision of law;
- Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

Count 9
Connecticut False Claims Act
(Conn. Gen. Stat. § 4-274, *et seq.* (2014))

239. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

240. This is a *qui tam* action brought by Relator on behalf of the State of Connecticut to recover treble damages and civil penalties under the Connecticut False Claims Act, Conn. Gen. Stat. § 17b-301a, *et seq.*

241. Conn. Gen. Stat. § 4-275 imposes liability as follows:

(a) No person shall:

(1) Knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval under a state-administered health or human services program;

(2) Knowingly make, use or cause to be made or used, a false record or statement material to a false or fraudulent claim under a state-administered health or human services program;

(3) Conspire to commit a violation of this section;

(4) Having possession, custody or control of property or money used, or to be used, by the state relative to a state-administered health or human services program, knowingly deliver, or cause to be delivered, less property than the amount for which the person receives a certificate or receipt;

(5) Being authorized to make or deliver a document certifying receipt of property used, or to be used, by the state relative to a state-administered health or human services program and intending to defraud the state, make or deliver such document without completely knowing that the information on the document is true;

(6) Knowingly buy, or receive as a pledge of an obligation or debt, public property from an officer or employee of the state relative to a state-administered health or human services program, who lawfully may not sell or pledge the property;

(7) Knowingly make, use or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state under a state-administered health or human services program; or

(8) Knowingly conceal or knowingly and improperly avoid or decrease an obligation to pay or transmit money or property to the state under a state-administered health or human services program.

242. Defendants violated the Connecticut False Claims Act and knowingly caused false claims to be made, used and presented to the State of Connecticut by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims

submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

243. The State of Connecticut, by and through the Connecticut Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

244. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Connecticut in connection with Defendants' conduct. Compliance with applicable Connecticut statutes was also a condition of payment of claims submitted to the State of Connecticut.

245. Had the State of Connecticut known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

246. As a result of Defendants' violations of the Connecticut False Claims Act, the State of Connecticut has been damaged in an amount far in excess of millions of dollars exclusive of interest.

247. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Connecticut False Claims Act on behalf of himself and the State of Connecticut.

248. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Connecticut in the operation of its Medicaid program.

249. WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the STATE OF CONNECTICUT:

- Three times the amount of actual damages which the State of Connecticut has sustained as a result of Defendants' conduct;
- A civil penalty of not less than $11,463 and not more than $23,331 for each false claim which Defendants caused to be presented to the State of Connecticut, except that this upper limit on liability is subject to an automatic adjustment in accordance with the CPIAA;
- Pre- and post-judgment interest; and
- All costs incurred in bringing this action.

To RELATOR:

- The maximum amount allowed pursuant to Connecticut False Claims Act, Conn. Gen. Stat. § 4-275 *et seq.* and/or any other applicable provision of law;
- Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

Count 10
Delaware False Claims and Reporting Act
(6 Del. C. §1201, *et seq.*)

250. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

251. This is a *qui tam* action brought by Relator on behalf of the State of Delaware to recover treble damages and civil penalties under the Delaware False Claims and Reporting Act, 6 Del. C. Ann. tit. 6 § 1201, *et seq.*

252. 6 Del. C. § 1201(a) in pertinent part provides for liability for any person who:

> (1) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (3) Conspires to commit a violation of paragraph (a)(1), (2), . . . or (7) of this section; or
>
> * * *
>
> (7) Knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.

253. Defendants violated the Delaware False Claims and Reporting Act, 6 Del. C. Ann. tit. 6 § 1201 *et seq.*, and knowingly caused false claims to be made, used and presented to the State of Delaware by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

254. The State of Delaware, by and through the Delaware Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

255. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and also an express condition of payment of claims submitted to the State of Delaware in connection with Defendants' conduct. Compliance with applicable Delaware statutes and regulations was also an express condition of payment of claims submitted to the State of Delaware.

256. Had the State of Delaware known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

257. As a result of Defendants' violations of the Delaware False Claims and Reporting Act, 6 Del. C. Ann. tit. 6 § 1201, *et seq.*, the State of Delaware has been damaged in an amount far in excess of millions of dollars exclusive of interest.

258. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Delaware False Claims and Reporting Act, 6 Del. C. Ann. tit. 6 § 1201, *et seq.*, on behalf of himself and the State of Delaware.

259. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Delaware in the operation of its Medicaid program.

260. WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the STATE OF DELAWARE:

- Three times the amount of actual damages which the State of Delaware has sustained as a result of Defendants' conduct;
- A civil penalty of not less than $10,951 and not more than $21,916 for each false claim which Defendants caused to be presented to the State of Delaware;
- Pre- and post-judgment interest; and
- All costs incurred in bringing this action.

To RELATOR:

- The maximum amount allowed pursuant to Delaware False Claims and Reporting Act, 6 Del. C. Ann. tit. 6 § 1201, and/or any other applicable provision of law;
- Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

Count 11
District of Columbia False Claims Law
(D.C. Code § 2-381.01, *et seq.* (2014)

261. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

262. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.

263. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

264. By virtue of the acts described above, Defendants conspired to violate the District of Columbia False Claims Act.

265. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

266. Defendants knowingly submitted and/or caused to be made or used false records or false statements in order to avoid or decrease their obligations to return overpayments of local and federal funds to the District of Columbia.

267. By reason of the Defendants' acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

268. Pursuant to D.C. Code Ann. § 2-308.02, the District of Columbia is entitled to three times the amount of actual damages plus a penalty of not less than $11,463 and not more than $23,331, as adjusted pursuant to D.C. Code Ann. § 2-308.10, for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants

Count 12
Florida False Claims Act
(Fla, Stat. Ann. §68.081 and §68.082(2)(a)-(b))

269. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

270. This is a *qui tam* action brought by Relator on behalf of the State of Florida to recover treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. § 68.081, *et seq.*

271. Fla. Stat. § 68.082(2) provides liability for any person who:

(a) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval;

(b) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim; or

(c) Conspires to commit a violation of this subsection.

272. Defendants further violated Fla. Stat. § 68.082(2) and knowingly caused false claims to be made, used and presented to the State of Florida by engaging in the conduct alleged

herein and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

273. The State of Florida, by and through the Florida Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

274. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Florida in connection with Defendants' conduct. Compliance with applicable Florida statutes was also a condition of payment of claims submitted to the State of Florida.

275. Had the State of Florida known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

276. As a result of Defendants' violations of Fla. Stat. § 68.082(2), the State of Florida has been damaged in an amount far in excess of millions of dollars exclusive of interest.

277. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Fla. Stat. § 68.083(2) on behalf of himself and the State of Florida.

278. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Florida in the operation of its Medicaid program

279. WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the STATE OF FLORIDA:

(1) Three times the amount of actual damages which the State of Florida has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Florida;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to Fla. Stat. § 68.085 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

Count 13
Georgia False Medical Claims Act
& Georgia Taxpayer Protection Against False Claims Act
Ga. Code Ann. 49-4-168, *et seq.* &
Ga. Code Ann. 23-3-120, et seq.

280. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

281. This is a *qui tam* action brought by Relator on behalf of the State of Georgia to recover treble damages and civil penalties under the Georgia False Medicaid Claims Act, Ga. Code Ann., § 49-4-168, *et seq.*

282. The Georgia False Medicaid Claims Act, Ga. Code Ann., § 49-4-168-1, imposes liability on any person who:

(1) Knowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;

(2) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim;

(3) Conspires to commit a violation of paragraph (1), (2), (4), (5), (6), or (7) of this subsection;

(4) Has possession, custody, or control of property or money used or to be used by the Georgia Medicaid program and knowingly delivers, or causes to be delivered, less than all of such property or money;

(5) Is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Georgia Medicaid program and, intending to defraud the Georgia Medicaid program, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Georgia Medicaid program who lawfully may not sell or pledge the property; or

(7) Knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit property or money to the Georgia Medicaid program, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit property or money to the Georgia Medicaid program.

283. Defendants violated the Georgia False Medicaid Claims Act and knowingly caused false claims to be made, used and presented to the State of Georgia by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

284. The State of Georgia, by and through the Georgia Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

285. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Georgia in connection with Defendants' conduct. Compliance with applicable Georgia statutes was also a condition of payment of claims submitted to the State of Georgia.

286. Had the State of Georgia known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

287. As a result of Defendants' violations of the Georgia False Medicaid Claims Act, the State of Georgia has been damaged in an amount far in excess of millions of dollars exclusive of interest

288. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Georgia False Medicaid Claims Act on behalf of himself and the State of Georgia.

289. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Georgia in the operation of its Medicaid program.

290. WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the STATE OF GEORGIA:

(1) Three times the amount of actual damages which the State of Georgia has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $11,463 and not more than $23,331 for each false claim which Defendants caused to be presented to the State of

Georgia;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to Georgia False Medicaid Claims Act, Ga. Code Ann., § 49-4-168, and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

Count 14
Hawaii False Claims Act
(Haw. Rev. Stat. § 661-21, *et seq.*)

291. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

292. This is a *qui tam* action brought by Relator on behalf of the State of Hawaii to recover treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21, *et seq.*

293. Section 661-21(a) provides liability for any person who:

(1) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

* * *

(6) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceals, or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State; or

* * *

(8) Conspires to commit any of the conduct described in this subsection.

294. Defendants violated Haw. Rev. Stat. § 661-21(a) and knowingly caused false claims to be made, used and presented to the State of Hawaii by the conduct alleged herein and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

295. The State of Hawaii, by and through the Hawaii Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

296. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Hawaii in connection with Defendants' conduct. Compliance with applicable Hawaii statutes was also a condition of payment of claims submitted to the State of Hawaii.

297. Had the State of Hawaii known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

298. As a result of Defendants' violations of Haw. Rev. Stat. § 661-21, the State of Hawaii has been damaged in an amount far in excess of millions of dollars exclusive of interest.

299. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Haw. Rev. Stat. § 661-21 on behalf of himself and the State of Hawaii.

300. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Hawaii in the operation of its Medicaid program.

301. WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the STATE OF HAWAII:

(1) Three times the amount of actual damages which the State of Hawaii has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $11,463 and not more than $23,331 for each false claim which Defendants caused to be presented to the State of Hawaii;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to Haw. Rev. Stat. § 661-21 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

Count 15
Illinois Whistleblower Reward and Protection Act
(740 ILCS 175, *et seq.*)

302. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

303. This is a *qui tam* action brought by Relator and the State of Illinois to recover treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175, *et seq.*

304. 740 ILCS 175/3(a) provides liability for any person who

(a) knowingly presents, or causes to be presented, to an officer or employee of the State of a member of the Guard a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

(c) conspires to defraud the State by getting a false or fraudulent claim allowed or paid;

(d) knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision.

305. In addition, 305 ILCS 5/8A-3(b) of the Illinois Public Aid Code (Vendor Fraud and Kickbacks) prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Illinois Medicaid program.

306. Defendants knowingly violated 740 ILCS 175/3(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Illinois from at least January 2010 to the present by violating the Illinois Anti-Kickback Statute 305 ILCS 5/8A-3(b) and the Federal Anti-Kickback Act, as described herein.

307. As a result of Defendants' off-label marketing and kickback schemes, all of the claims that Horizon knowingly caused physicians and pharmacists to knowingly submit to the Illinois Medicaid program are false or fraudulent. Further, Horizon knowingly caused physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Anti-Kickback Statute and the Illinois Anti- Kickback Statute

(305 ILCS 5/8A-3(b)). Compliance with federal and state laws and regulations was a condition of payment.

308. The State of Illinois, by and through the Illinois Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

309. Given the structure of the health care systems, the false statements, representations, and records made by Horizon had the potential to influence the State of Illinois's payment decision.

310. The ultimate submission by physicians, pharmacies, and third-party payers of false and/or fraudulent claims to the state Medicaid program was a foreseeable factor in the State of Illinois's loss, and a consequence of the scheme.

311. As a result of Defendants' violations of 740 ILCS 175/3(a), the State of Illinois has been damaged.

312. There are no bars to recovery under 740 ILCS 175/4(e)(4), and, or in the alternative, Relator is an original source as defined therein. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 740 ILCS 175/4(b) on behalf of herself and the State of Illinois.

313. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Illinois in the operation of its Medicaid program.

314. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF ILLINOIS:

- Three times the amount of actual damages that the State of Illinois has sustained as a result of Defendants' fraudulent and illegal practices;

- A civil penalty of not less than $11,463 and not more than $23,331 for each false claim that Defendants caused to be presented to the State of Illinois;

- Prejudgment interest; and

- All costs incurred in bringing this action.

To RELATOR:

- The maximum amount allowed pursuant to 740 ILCS 175/4(d) and/or any other applicable provision of law.

Count 16
Illinois Insurance Claims Fraud Prevention Act
740 Ill. Comp. Stat. § 92/1, *et seq.*)

315. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

316. This is a claim for treble damages and penalties under the IICFPA.

317. Pursuant to 740 Ill. Comp. Stat. § 92/5(a):

> A person who violates any provision of this Act, . . . or Section 17-10.5 of the Criminal Code . . . shall be subject, in addition to any other penalties that may be prescribed by law, to a civil penalty of not less than $5,000 nor more than $10,000, plus an assessment of not more than 3 times the amount of each claim for compensation under a contract of insurance

318. 740 Ill. Comp. Stat. § 5/17-10.5 provides, in pertinent part:

> (a) Insurance fraud.
>
> (1) A person commits insurance fraud when he or she knowingly obtains, attempts to obtain, or causes to be obtained, by deception, control over the property of an insurance company or self-insured entity by the making of a false claim or by causing a false claim to be made on any policy of insurance issued by an insurance company or by the making of a false claim or by causing a false claim to be made to a self-insured entity, intending to deprive an insurance company or self-insured entity permanently of the use and benefit of that property.
>
> (2) A person commits health care benefits fraud against a provider, other than a governmental unit or agency, when he or she knowingly

> obtains or attempts to obtain, by deception, health care benefits and that obtaining or attempt to obtain health care benefits does not involve control over property of the provider.
>
> * * *
>
> (c) Conspiracy to commit insurance fraud. . . .

319. By virtue of the acts described above, Defendants knowingly presented or caused to be presented false or fraudulent claims to the private insurers in Illinois, or for patients in Illinois that those insurers covered, for payment or approval in violation of each patient's private health insurance contract.

320. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements and omitted material facts to induce the private insurers in Illinois, or for patients in Illinois covered by those insurers, to approve or pay such false and fraudulent claims.

321. Defendants knowingly presented or caused to be presented false or fraudulent claims to the private insurers in Illinois, or for patients in Illinois those insurers covered, for payment or approval in violation of each patient's private health insurance contract.

322. By virtue of the acts described above, Defendants knowingly utilized a scheme by which it presented, or caused to be presented, false or fraudulent claims to private insurers in Illinois, or for patients in Illinois that those insurers covered (i.e., patients who hold private insurance contracts and against whom Defendants could file claims for payment or approval) in violation of each patient's private health insurance contract.

323. By virtue of the acts described above, Defendants conspired to violate the IICFPA and each patient's private health insurance contract.

324. The private insurers in Illinois, or those insurers that covered patients in Illinois, unaware of the falsity of the records, statements and claims made, used, presented, or caused to

be presented by Defendants, paid and continue to pay the claims that are non-payable as a result of Defendants' illegal conduct.

325. Defendants knowingly submitted and/or caused to be made or used false records or false statements in order to avoid or decrease its obligations to return overpayments to these private insurance companies.

326. By reason of Defendants' acts, these private insurance companies have been damaged, and continue to be damaged, in a substantial amount to be determined at trial.

327. Each claim for reimbursement that was a result of Defendants' scheme represents a false or fraudulent record or statement and a false or fraudulent claim for payment.

328. State of Illinois is entitled to the maximum penalty of $10,000 per violation, plus an assessment of three times the amount of each false or fraudulent claim for compensation made, used, presented, or caused to be made, used, or presented by Defendants.

Count 17
Indiana False Claims and Whistleblower Protection Act
(Ind. Code § 5-11-5.5, *et seq.*)

329. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

330. This is a *qui tam* action brought by Relator on behalf of the State of Indiana to recover treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, Ind. Code 5-11-5.5-2, which imposes liability on:

> A person who knowingly or intentionally:
>
> (1) presents a false claim to the state for payment or approval;
>
> (2) makes or uses a false record or statement to obtain payment or approval of a false claim from the state;
>
> (3) with intent to defraud the state, delivers less money or property to the state than the amount recorded on the certificate or receipt the

person receives from the state;

(4) with intent to defraud the state, authorizes issuance of a receipt without knowing that the information on the receipt is true;

(5) receives public property as a pledge of an obligation on a debt from an employee who is not lawfully authorized to sell or pledge the property;

(6) makes or uses a false record or statement to avoid an obligation to pay or transmit property to the state;

(7) conspires with another person to perform an act described in subdivisions (1) through (6); or

(8) causes or induces another person to perform an act described in subdivisions (1) through (6) . . . .

331. Defendants violated the Indiana False Claims Act and knowingly caused false claims to be made, used and presented to the State of Indiana by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

332. The State of Indiana, by and through the Indiana Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

333. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Indiana in connection with Defendants' conduct. Compliance with applicable Indiana statutes was also a condition of payment of claims submitted to the State of Indiana.

334. Had the State of Indiana known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were

premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

335. As a result of Defendants' violations of Indiana's False Claims Act, the State of Indiana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

336. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Ind. Code § 5-11-5.5, *et seq.* on behalf of himself and the State of Indiana.

337. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Indiana in the operation of its Medicaid program.

338. WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the STATE OF INDIANA:

(1) Three times the amount of actual damages which the State of Indiana has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $11,463 and not more than $23,331 for each false claim which Defendants caused to be presented to the State of Indiana, except that this upper limit on liability is subject to an automatic adjustment in accordance with the CPIAA;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to Ind. Code § 5-11-5.5 *et seq.* and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

Count 18
Iowa False Claims Law
(I.C.A. § 685.1, *et seq.*)

339. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

340. This is a *qui tam* action brought by Relator on behalf of the State of Iowa to recover treble damages and civil penalties under the Iowa False Claims Law, I.C.A. § 685.1, *et seq.*

341. Iowa False Claims Law, I.C.A. § 685.2, in pertinent part provides for liability for any person who:

> (a) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.
>
> (b) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.
>
> (c) Conspires to commit a violation of paragraph "a", "b" . . . .

342. Defendants violated the Iowa False Claims Law, I.C.A. § 685.1, *et seq.* and knowingly caused false claims to be made, used and presented to the State of Iowa by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

343. The State of Iowa, by and through the Iowa Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

344. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Iowa in

connection with Defendants' conduct. Compliance with applicable Iowa statutes was also a condition of payment of claims submitted to the State of Iowa.

345. Had the State of Iowa known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

346. As a result of Defendants' violations of the Iowa False Claims Law, I.C.A. § 685.1, *et seq.*, the State of Iowa has been damaged in an amount far in excess of millions of dollars exclusive of interest.

347. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Iowa False Claims Law, I.C.A. § 685.1, *et seq.*, on behalf of himself and the State of Iowa.

348. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Iowa in the operation of its Medicaid program.

349. WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the STATE OF IOWA:

(1) Three times the amount of actual damages which the State of Iowa has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $11,463 and not more than $23,331 for each false claim which Defendants caused to be presented to the State of Iowa, except that this upper limit on liability is subject to an automatic adjustment in accordance with the CPIAA;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to Iowa False Claims Law, I.C.A. § 685.1 *et seq.* and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

Count 19
Louisiana Medical Assistance Programs Integrity Law
(La. Rev. Stat. Ann. § 46:437.1, *et seq.*)

350. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

351. This is a *qui tam* action brought by Relator on behalf of the State of Louisiana to recover treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 437.1, *et seq.*

352. La. Rev. Stat. Ann. § 46:438.3 provides:

(A) No person shall knowingly present or cause to be presented a false or fraudulent claim.

(B) No person shall knowingly engage in misrepresentation or make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim.

(C) No person shall knowingly make, use, or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the medical assistance programs, or to knowingly conceal, avoid, or decrease an obligation to pay or transmit money or property to the medical assistance programs.

(D) No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim.

353. Defendants further violated La. Rev. Stat. Ann. § 46:438.3 and knowingly caused false claims to be made, used and presented to the State of Louisiana by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

354. The State of Louisiana, by and through the Louisiana Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

355. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and also an express condition of payment of claims submitted to the State of Louisiana in connection with Defendants' conduct. Compliance with applicable Louisiana statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Louisiana.

356. Had the State of Louisiana known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

357. As a result of Defendants' violations of La. Rev. Stat. Ann. § 46:438.3, the State of Louisiana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

358. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to La. Rev. Stat. Ann. § 46:439.1(A) on behalf of himself and the State of Louisiana.

359. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Louisiana in the operation of its Medicaid program.

360. WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the STATE OF LOUISIANA:

(1) Three times the amount of actual damages which the State of Louisiana has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $11,463 and not more than $23,331 for each false claim which Defendants caused to be presented to the State of Louisiana, except that this upper limit on liability is subject to an automatic adjustment in accordance with the CPIAA;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to La. Rev. Stat. § 439.4(A) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

Count 20
Maryland False Claims Act
(Md. Code Ann. Health - Gen., § 2-601 *et seq.*)

361. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

362. This is a *qui tam* action brought by Relator on behalf of the State of Maryland to recover treble damages and civil penalties under the Maryland False Claims Act, Md. Code Ann. Health - Gen., § 2-601, *et seq.*

363. Section 2-602 of Maryland's False Claims Act imposes liability as follows

(a) A person may not:

(1) Knowingly present or cause to be presented a false or fraudulent claim for payment or approval;

(2) Knowingly make, use, or cause to be made or used a false record or statement material to a false or fraudulent claim;

(3) Conspire to commit a violation under this subtitle;

(4) Have possession, custody, or control of money or other property used by or on behalf of the State under a State health plan or a State health program and knowingly deliver or cause to be delivered to the State less than all of that money or other property;

(5) (i) Be authorized to make or deliver a receipt or other document certifying receipt of money or other property used or to be used by the State under a State health plan or a State health program; and (ii) Intending to defraud the State or the Department, make or deliver a receipt or document knowing that the information contained in the receipt or document is not true;

(6) Knowingly buy or receive as a pledge of an obligation or debt publicly owned property from an officer, employee, or agent of a State health plan or a State health program who lawfully may not sell or pledge the property;

(7) Knowingly make, use, or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or other property to the State;

(8) Knowingly conceal, or knowingly and improperly avoid or decrease, an obligation to pay or transmit money or other property to the State; or

(9) Knowingly make any other false or fraudulent claim against a State health plan or a State health program.

364. Defendants violated the Maryland False Claims Act, and knowingly caused false claims to be made, used and presented to the State of Maryland by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

365. The State of Maryland, by and through the Maryland Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

366. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and an express condition of payment of claims submitted to the State of Maryland in connection with Defendants' conduct. Compliance with applicable Maryland statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Maryland.

367. Had the State of Maryland known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

368. As a result of Defendants' violations of the Maryland False Claims Act, the State of Maryland has been damaged in an amount far in excess of millions of dollars exclusive of interest.

369. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Maryland False Claims Act on behalf of himself and the State of Maryland.

370. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Maryland in the operation of its Medicaid program.

371. WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the STATE OF MARYLAND:

(1) Three times the amount of actual damages which the State of Maryland has sustained as a result of Defendants' conduct;

(2) A civil penalty of not more than $10,000 for each false claim which Defendants caused to be presented to the State of Maryland;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to Maryland False Claims Act and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

Count 21
Massachusetts False Claims Act
(Mass. Gen. Laws Ann. Ch. 12 § 5(A), *et seq.*)

372. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

373. This is a *qui tam* action brought by Relator on behalf of the Commonwealth of Massachusetts for treble damages and penalties under Massachusetts False Claims Act, Mass. Gen. Laws Ann. Ch. 12 § 5(A), *et seq.*

374. Mass. Gen. Laws Ann. Ch. 12 § 5B(a) provides liability for any person who:

> (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (2) knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim; or
>
> (3) conspires to commit a violation of this subsection; or
>
> * * *
>
> (10) is a beneficiary of an inadvertent submission of a false claim to the common wealth or political subdivision thereof, or is a beneficiary of an overpayment from the commonwealth or a political subdivision thereof, and who subsequently discovers the falsity of the claim or the receipt of overpayment, and fails to disclose the false claim or receipt of overpayment to the commonwealth or a political subdivision by the later of:
>
> (i) the date which is 60 days after the date on which the false claim or receipt of overpayment was identified; or
>
> (ii) the date any corresponding cost report is due . . . .

375. Defendants violated Mass. Gen. Laws Ann. Ch. 12 § 5B and knowingly caused false claims to be made, used and presented to the Commonwealth of Massachusetts by the conduct alleged herein and by virtue of the fact that none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

376. The Commonwealth of Massachusetts, by and through the Massachusetts Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

377. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the Commonwealth of Massachusetts in connection with Defendants' conduct. Compliance with applicable Massachusetts statutes was also a condition of payment of claims submitted to the Commonwealth of Massachusetts.

378. Had the Commonwealth of Massachusetts known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

379. As a result of Defendants' violations of Mass. Gen. Laws Ann. Ch. 12 § 5B, the Commonwealth of Massachusetts has been damaged in an amount far in excess of millions of dollars exclusive of interest.

380. Relator is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to Mass. Gen. Laws Ann. Ch. 12 § 5(c)(2) on behalf of himself and the Commonwealth of Massachusetts.

381. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts

separate damage to the Commonwealth of Massachusetts in the operation of its Medicaid program.

382. WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the Commonwealth OF MASSACHUSETTS:

(1) Three times the amount of actual damages which the Commonwealth of Massachusetts has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $11,463 and not more than $23,331 for each false claim which Defendants caused to be presented to the Commonwealth of Massachusetts, except that this upper limit on liability is subject to an automatic adjustment in accordance with the CPIAA;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to Mass. Gen. Laws Ann. Ch. 12, § 5F and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

Count 22
Michigan Medicaid False Claims Act
(Mich. Comp. Laws § 400.601, *et seq.*)

383. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

384. This is a *qui tam* action brought by Relator on behalf of the State of Michigan to recover treble damages and civil penalties under Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.603, which provides in pertinent part:

> (1) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact in an application for Medicaid benefits.
>
> (2) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact for use in determining rights to a Medicaid benefit. . . .

385. Defendants violated Michigan law and knowingly caused false claims to be made, used and presented to the State of Michigan by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

386. The State of Michigan, by and through the Michigan Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

387. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Michigan in connection with Defendants' conduct. Compliance with applicable Michigan statutes was also a condition of payment of claims submitted to the State of Michigan.

388. Had the State of Michigan known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

389. As a result of Defendants' violations of the Medicaid False Claims Act, the State of Michigan has been damaged in an amount far in excess of millions of dollars exclusive of interest.

390. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Medicaid False Claims Act on behalf of himself and the State of Michigan.

391. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Michigan in the operation of its Medicaid program.

392. WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the STATE OF MICHIGAN:

(1) Three times the amount of actual damages which the State of Michigan has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Michigan;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to the Medicaid False Claims Act and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

Count 23
Minnesota False Claims Act
(M.S.A. § 15C.01, *et seq.*)

393. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

394. This is a *qui tam* action brought by Relator on behalf of the State of Minnesota to recover treble damages and civil penalties under the Minnesota False Claims Act, M.S.A. § 15C.01, *et seq.*

395. Minnesota False Claims Act, M.S.A. § 15C.02, provides for liability for any person who:

> (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (2) knowingly makes or uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (3) knowingly conspires to commit a violation of clause (1), (2), (4), (5), (6), or (7);
>
> (4) has possession, custody, or control of property or money used, or to be used, by the state or a political subdivision and knowingly delivers or causes to be delivered less than all of that money or property;
>
> (5) is authorized to make or deliver a document certifying receipt for money or property used, or to be used, by the state or a political subdivision and, intending to defraud the state or a political subdivision, makes or delivers the receipt without completely knowing that the information on the receipt is true;
>
> (6) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the state or a political subdivision who lawfully may not sell or pledge the property; or
>
> (7) knowingly makes or uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state or a political subdivision, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state or a political subdivision.

396. Defendants violated the Minnesota False Claims Act and knowingly caused false claims to be made, used and presented to the State of Minnesota by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims

submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

397. The State of Minnesota, by and through the Minnesota Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

398. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Minnesota in connection with Defendants' conduct. Compliance with applicable Minnesota statutes was also a condition of payment of claims submitted to the State of Minnesota.

399. Had the State of Minnesota known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

400. As a result of Defendants' violations of the Minnesota False Claims Act, the State of Minnesota has been damaged in an amount far in excess of millions of dollars exclusive of interest.

401. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Minnesota False Claims Act on behalf of himself and the State of Minnesota.

402. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Minnesota in the operation of its Medicaid program.

403. WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the STATE OF MINNESOTA:

(1) Three times the amount of actual damages which the State of Minnesota has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $11,463 and not more than $23,331 for each false claim which Defendants caused to be presented to the State of Minnesota;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to Minnesota False Claims Act and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

Count 24
Montana False Claims Act
(MCA § 17-8-401, *et seq.*)

404. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

405. This is a *qui tam* action brought by Relator on behalf of the State of Montana to recover treble damages and civil penalties under the Montana False Claims Act, MCA § 17-8-401, *et seq.*

406. Montana's False Claims Act, MCA § 17-8-403, provides for liability for any person who:

(a) knowingly presents or causes to be presented a false or fraudulent

claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim;

(c) conspires to commit a violation of this subsection (1);

(d) has possession, custody, or control of public property or money used or to be used by the governmental entity and knowingly delivers or causes to be delivered less than all of the property or money;

(e) is authorized to make or deliver a document certifying receipt of property used or to be used by the governmental entity and, with the intent to defraud the governmental entity or to willfully conceal the property, makes or delivers a receipt without completely knowing that the information on the receipt is true;

(f) knowingly buys or receives as a pledge of an obligation or debt public property of the governmental entity from any person who may not lawfully sell or pledge the property;

(g) knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to a governmental entity or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to a governmental entity; or

(h) as a beneficiary of an inadvertent submission of a false or fraudulent claim to the governmental entity, subsequently discovers the falsity of the claim or that the claim is fraudulent and fails to disclose the false or fraudulent claim to the governmental entity within a reasonable time after discovery of the false or fraudulent claim.

407. Defendants violated the Montana False Claims Act and knowingly caused false claims to be made, used and presented to the State of Montana by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

408. The State of Montana, by and through the Montana Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

409. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Montana in connection with Defendants' conduct. Compliance with applicable Montana statutes was also a condition of payment of claims submitted to the State of Montana.

410. Had the State of Montana known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

411. As a result of Defendants' violations of the Montana False Claims Act, the State of Montana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

412. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Montana False Claims Act on behalf of himself and the State of Montana.

413. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Montana in the operation of its Medicaid program.

414. WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the STATE OF MONTANA:

(1) Three times the amount of actual damages which the State of Montana has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Montana;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to Montana False Claims Act and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

Count 25
Nevada False Claims Act
(Nev. Rev. Stat. Ann. § 357.010, *et seq.*)

415. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

416. This is a *qui tam* action brought by Relator on behalf of the State of Nevada to recover treble damages and civil penalties under the Nevada False Claims Act, Nev. Rev. Stat. Ann. § 357.010, *et seq.*

417. N.R.S. § 357.040(1) provides liability for any person who:

(a) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval.

(b) Knowingly makes or uses, or causes to be made or used, a false record or statement that is material to a false or fraudulent claim.

(c) Has possession, custody or control of public property or money used

or to be used by the State or a political subdivision and knowingly delivers or causes to be delivered to the State or a political subdivision less money or property than the amount of which the person has possession, custody or control.

(d) Is authorized to prepare or deliver a document that certifies receipt of money or property used or to be used by the State or a political subdivision and knowingly prepares or delivers such a document without knowing that the information on the document is true.

(e) Knowingly buys, or receives as a pledge or security for an obligation or debt, public property from a person who is not authorized to sell or pledge the property.

(f) Knowingly makes or uses, or causes to be made or used, a false record or statement that is material to an obligation to pay or transmit money or property to the State or a political subdivision.

(g) Knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State or a political subdivision.

(h) Is a beneficiary of an inadvertent submission of a false claim and, after discovering the falsity of the claim, fails to disclose the falsity to the State or political subdivision within a reasonable time.

(i) Conspires to commit any of the acts set forth in this subsection.

418. Defendants violated N.R.S. § 357.040(1) and knowingly caused false claims to be made, used and presented to the State of Nevada by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

419. The State of Nevada, by and through the Nevada Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

420. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Nevada in

connection with Defendants' conduct. Compliance with applicable Nevada statutes was also a condition of payment of claims submitted to the State of Nevada.

421. Had the State of Nevada known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

422. As a result of Defendants' violations of N.R.S. § 357.040(1), the State of Nevada has been damaged in an amount far in excess of millions of dollars exclusive of interest.

423. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.R.S. § 357.080(1) on behalf of himself and the State of Nevada.

424. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Nevada in the operation of its Medicaid program.

425. WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the STATE OF NEVADA:

(1) Three times the amount of actual damages which the State of Nevada has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $11,463 and not more than $23,331 for each false claim which Defendants caused to be presented to the State of Nevada, except that this upper limit on liability is subject to an automatic adjustment in accordance with the CPIAA;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to N.R.S. § 357.040 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

Count 26
New Hampshire Medicaid Fraud and False Claims Act
(N.H. R.S.A. Title 22, Ch. 167, *et seq.*)

426. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

427. This is a *qui tam* action brought by Relator on behalf of the State of New Hampshire to recover treble damages and civil penalties under the Medicaid Fraud and False Claims Act, R.S.A. §§ 167:58, *et seq.*

428. Under R.S.A. § 167:61-b, no person shall:

(a) Knowingly presents, or causes to be presented, to an officer or employee of the department, a false or fraudulent claim for payment or approval.

(b) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the department.

(c) Conspires to defraud the department by getting a false or fraudulent claim allowed or paid.

(d) Has possession, custody, or control of property or money used, or to be used, by the department and, intending to defraud the department or willfully to conceal the property, delivers, or causes to be delivered, less property than the amount for which the person receives a certificate or receipt.

(e) Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the department.

(f) Is a beneficiary of an inadvertent submission of a false claim to the department, who subsequently discovers the falsity of the claim, and fails to

disclose the false claim to the department within a reasonable time after discovery of the false claim.

429. Defendants violated R.S.A. § 167:61-b, and knowingly caused false claims to be made, used and presented to the State of New Hampshire by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

430. The State of New Hampshire, by and through the New Hampshire Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

431. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of New Hampshire in connection with Defendants' conduct. Compliance with applicable New Hampshire statutes was also a condition of payment of claims submitted to the State of New Hampshire.

432. Had the State of New Hampshire known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

433. As a result of Defendants' violations of R.S.A. § 167:61-b, the State of New Hampshire has been damaged in an amount far in excess of millions of dollars exclusive of interest.

434. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to R.S.A. § 167:61-c (II), on behalf of himself and the State of New Hampshire.

435. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Hampshire in the operation of its Medicaid program.

436. WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the STATE OF NEW HAMPSHIRE:

(1) Three times the amount of actual damages which the State of New Hampshire has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of New Hampshire;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to R.S.A. § 167:61-e and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

Count 27
New Jersey False Claims Act
(N.J.S.A. § 2A:32C-1, *et seq.*)

437. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

438. This is a *qui tam* action brought by Relator on behalf of the State of New Jersey to recover treble damages and civil penalties under the New Jersey False Claims Act, N.J.S.A. § 2A:32C-1, *et seq.*

439. N.J.S.A. § 2A:32C-3, provides for liability for any person who:

(a) Knowingly presents or causes to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;

(b) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State;

(c) Conspires to defraud the State by getting a false or fraudulent claim allowed or paid by the State;

(d) Has possession, custody, or control of public property or money used or to be used by the State and knowingly delivers or causes to be delivered less property than the amount for which the person receives a certificate or receipt;

(e) Is authorized to make or deliver a document certifying receipt of property used or to be used by the State and, intending to defraud the entity, makes or delivers a receipt without completely knowing that the information on the receipt is true;

(f) Knowingly buys, or receives as a pledge of an obligation or debt, public property from any person who lawfully may not sell or pledge the property; or

(g) Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.

440. Defendants violated the New Jersey False Claims Act and knowingly caused false claims to be made, used and presented to the State of New Jersey by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

441. The State of New Jersey, by and through the New Jersey Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

442. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of New Jersey in connection with Defendants' conduct. Compliance with applicable New Jersey statutes was also a condition of payment of claims submitted to the State of New Jersey.

443. Had the State of New Jersey known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

444. As a result of Defendants' violations of the New Jersey False Claims Act, the State of New Jersey has been damaged in an amount far in excess of millions of dollars exclusive of interest.

445. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the New Jersey False Claims Act on behalf of himself and the State of New Jersey.

446. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Jersey in the operation of its Medicaid program.

447. WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the STATE OF NEW JERSEY:

(1) Three times the amount of actual damages which the State of New Jersey has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $11,463 and not more than $23,331 for each false claim which Defendants caused to be presented to the State of New Jersey;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to New Jersey False Claims Act and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

Count 28
New Jersey Medical Assistance & Health Services Act
(N.J.S.A. 30:4D-1, *et seq.*)

448. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

449. The New Jersey Medical Assistance and Health Services Act ("NJMAHS"), N.J.S.A. 30:4D-1, *et seq.*, is aimed at providing medical assistance to residents with limited resources, but also provides FCA-like protections in the event of a violation.

450. Pursuant to N.J.S.A. 30:4D-17(b), it is illegal for any provider, or any person, firm, partnership, or entity to:

(1) Knowingly and willfully make or cause to be made any false statement or representation of a material fact in any cost study, claim form, or any document necessary to apply for or receive any benefit or payment under P.L.1968, c.413; or

(2) At any time knowingly and willfully make or cause to be made any false statement, written or oral, of a material fact for use in determining rights to such benefit or payment under P.L.1968, c.413; or

(3) Conceal or fail to disclose the occurrence of an event which

(i) affects a person's initial or continued right to any such benefit or payment, or

(ii) affects the initial or continued right to any such benefit or payment of any provider or any person, firm, partnership, corporation, or other entity in whose behalf a person has applied for or is receiving such benefit or payment with an intent to fraudulently secure benefits or payments not authorized under P.L.1968, c.413 or in a greater amount than that which is authorized under P.L.1968, c.413; or

(4) Knowingly and willfully convert benefits or payments or any part thereof received for the use and benefit of any provider or any person, firm, partnership, corporation, or other entity to a use other than the use and benefit of such provider or such person, firm, partnership, corporation, or entity . . . .

451. In addition to any other penalties provided by law, violators of the NJMAHS shall be liable for civil penalties of: (1) payment of interest on the amount of the excess benefits or payments at the maximum legal rate in effect on the date the payment was made; (2) payment of an amount not to exceed three-fold the amount of such excess benefits or payments; and (3) payment in the sum of not less than and not more than the civil penalty allowed under the federal False Claims Act, as it may be adjusted for inflation, for each claim for assistance, benefits or payment. N.J.S.A. 30:4D-17(e).

452. In this matter, Defendants submitted bills to the New Jersey State Government for payment and retained improperly obtained payments arising from their illegal off-label promotion and sale of Krystexxa. All such false claims were knowingly submitted to get false or fraudulent claims paid or approved by the New Jersey State Government.

453. As a result of Defendants' acts, the State of New Jersey has been damaged, and continues to be damaged, in a substantial amount to be determined at trial, and the State of New

Jersey is entitled to penalty of not less than $11,463 and not more than $23,331 for each false or fraudulent claim, plus three times the amount of damages which the State sustains arising from Defendants' unlawful conduct as described herein

Count 29
New Mexico Medicaid False Claims Act
(N.M. Stat. Ann. § 27-14-1, *et seq.*)
New Mexico Fraud Against Taxpayers Act
(N.M. Stat. Ann. § 44-9-1, *et seq.*)

454. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

455. This is a *qui tam* action brought by Relator on behalf of the State of New Mexico to recover treble damages and civil penalties under the New Mexico Fraud Against Taxpayers Act, which provides in pertinent part:

> A person shall not:
>
> (1) knowingly present, or cause to be presented, to an employee, officer or agent of the state or a political subdivision or to a contractor, grantee, or other recipient of state funds or political subdivision funds a false or fraudulent claim for payment or approval;
>
> (2) knowingly make or use, or cause to be made or used, a false, misleading or fraudulent record or statement to obtain or support the approval of or the payment on a false or fraudulent claim; or
>
> (3) conspire to defraud the state or a political subdivision by obtaining approval or payment on a false or fraudulent claim . . . .
>
> N.M. Stat. Ann. § 44-9-3(A)(1)-(3).

456. Defendants violated N.M. Stat. Ann. §§ 27-14-1, *et seq.* and N.M. Stat. Ann. § 44-9-1 *et seq.* and knowingly caused false claims to be made, used and presented to the State of New Mexico by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

457. The State of New Mexico, by and through the New Mexico Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

458. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of New Mexico in connection with Defendants' conduct. Compliance with applicable New Mexico statutes was also a condition of payment of claims submitted to the State of New Mexico.

459. Had the State of New Mexico known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

460. As a result of Defendants' violations of N.M. Stat. Ann. §§ 27-14-1 *et seq.* and N.M. Stat. Ann. § 44-9-1 *et seq.*, the State of New Mexico has been damaged in an amount far in excess of millions of dollars exclusive of interest.

461. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.M. Stat. Ann. §§ 27-14-1, *et seq.* and N.M. Stat. Ann. § 44-9-1, *et seq.* on behalf of himself and the State of New Mexico.

462. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Mexico in the operation of its Medicaid program.

463. WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the STATE OF NEW MEXICO:

(1) Three times the amount of actual damages which the State of New Mexico has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $11,463 and not more than $23,331 for each false claim which Defendants caused to be presented to the State of New Mexico;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to N.M. Stat. Ann. §§ 27-14-1 *et seq.* and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

Count 30
New York False Claims Act
(N.Y. State Fin. Law § 187, *et seq.*)

464. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

465. This is a *qui tam* action brought by Relator and the State of New York to recover treble damages and civil penalties under the New York False Claims Act, N.Y. State Fin. Law§ 187, *et seq.*

466. N.Y. State Fin. Law§ 189 provides liability for any person who-

a. knowingly presents, or causes to be presented, to any employee, officer or agent of the state or a local government, a false or fraudulent claim for payment or approval;

b. knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or a local government;

c. conspires to defraud the state or a local government by getting a false or fraudulent claim allowed or paid.

467. Defendants knowingly violated N.Y. State Fin. Law § 189 and knowingly caused thousands of false claims to be made, used and presented to the State of New York during the Covered Period by violating the Federal Anti-Kickback Act, as described herein.

468. As a result of Defendants'' off-label marketing and kickback schemes, all of the claims that Defendants knowingly caused physicians and pharmacists to knowingly submit to the New York Medicaid program are false or fraudulent. Further, Defendants knowingly caused physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Federal Anti-Kickback Statute. Compliance with federal and state laws and regulations was a condition of payment.

469. The State of New York, by and through the New York Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

470. Given the structure of the health care systems, the false statements, representations, and records made by Horizon had the potential to influence the State of New York's payment decision

471. The ultimate submission by physicians, pharmacists, and third-party payers of false and/or fraudulent claims to the state Medicaid program was a foreseeable factor in the State of New York's loss, and a consequence of the scheme.

472. As a result of Defendants' violations of N.Y. State Fin. Law§ 189, the State of New York has been damaged.

473. There are no bars to recovery under N.Y. Fin. Law § 190(9) and, or in the alternative, Relator is an original source as defined therein. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.Y. State Fin. Law§ 190(2) on behalf of herself and the State of New York.

474. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New York in the operation of its Medicaid program. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF NEW YORK:

(1) Three times the amount of actual damages which the State of New York has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $11,463 and not more than $23,331 for each false claim which Defendants caused to be presented to the State of New York;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to the New York State False Claims Act, and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

Count 31
North Carolina False Claims Act
N.C. Gen. Stat. Ann. § 1-605, *et seq.*)

475. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

476. This is a *qui tam* action brought by Relator on behalf of the State of North Carolina to recover treble damages and civil penalties under the North Carolina False Claims Act, N.C. Gen. Stat. Ann. § 1-605, *et seq.*

477. North Carolina's False Claims Act, N.C.G.S.A. § 1-607(a), provides for liability for any person who:

> (1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval.
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.
>
> (3) Conspires to commit a violation of subdivision (1), (2), (4), (5), (6), or (7) of this section.
>
> (4) Has possession, custody, or control of property or money used or to be used by the State and knowingly delivers or causes to be delivered less than all of that money or property.
>
> (5) Is authorized to make or deliver a document certifying receipt of property used or to be used by the State and, intending to defraud the State, makes or delivers the receipt without completely knowing that the information on the receipt is true.
>
> (6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from any officer or employee of the State who lawfully may not sell or pledge the property.
>
> (7) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State.

478. Defendants violated the North Carolina False Claims Act, and knowingly caused false claims to be made, used and presented to the State of North Carolina by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

479. The State of North Carolina, by and through the North Carolina Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.\

480. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and an express condition of payment of claims submitted to the State of North Carolina in connection with Defendants' conduct. Compliance with applicable North Carolina statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of North Carolina.

481. Had the State of North Carolina known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

482. As a result of Defendants' violations of the North Carolina False Claims Act, the State of North Carolina has been damaged in an amount far in excess of millions of dollars exclusive of interest.

483. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the North Carolina False Claims Act on behalf of himself and the State of North Carolina.

484. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of North Carolina in the operation of its Medicaid program.

485. WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the STATE OF NORTH CAROLINA:

(1) Three times the amount of actual damages which the State of North Carolina has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $11,463 and not more than $23,331 for each false claim which Defendants caused to be presented to the State of North Carolina;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to North Carolina False Claims Act and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

Count 32
Oklahoma Medicaid False Claims Act
Okl. Stat. Ann. Tit. 63, § 5053, *et seq.*)

486. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

487. This is a *qui tam* action brought by Relator on behalf of the State of Oklahoma to recover treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, 63 Okl. Stat. Ann. Tit. 63, § 5053, *et seq.*

488. Oklahoma's Medicaid False Claims Act, 63 Okl. St. Ann. § 5053.1, provides for liability for any person who:

> (1) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (3) Conspires to commit a violation of the Oklahoma Medicaid False Claims Act;
>
> (4) Has possession, custody, or control of property or money used, or to be used, by the state knowingly delivers, or causes to be delivered, less than all of such money or property;
>
> (5) Is authorized to make or deliver a document certifying receipt of property used or to be used by the state and, intending to defraud the state, makes or delivers the receipt without completely knowing that the information on the receipt is true;
>
> (6) Knowingly buys or receives as a pledge of an obligation or debt, public property from an officer or employee of the state who lawfully may not sell or pledge the property; or
>
> (7) Knowingly makes, uses or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state.

489. Defendants violated the Oklahoma Medicaid False Claims Act and knowingly caused false claims to be made, used and presented to the State of Oklahoma by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

490. The State of Oklahoma, by and through the Oklahoma Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

491. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and also an express condition of payment of claims submitted to the State of Oklahoma in connection with Defendants' conduct. Compliance with applicable Oklahoma statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Oklahoma.

492. Had the State of Oklahoma known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

493. As a result of Defendants' violations of the Oklahoma Medicaid False Claims Act, the State of Oklahoma has been damaged in an amount far in excess of millions of dollars exclusive of interest.

494. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Oklahoma Medicaid False Claims Act on behalf of himself and the State of Oklahoma. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Oklahoma in the operation of its Medicaid program.

495. WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the STATE OF OKLAHOMA:

(1) Three times the amount of actual damages which the State of Oklahoma has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $11,463 and not more than $23,331 for each false claim which Defendants caused to be presented to the State of Oklahoma;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to Oklahoma Medicaid False Claims Act and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

Count 33
Rhode Island False Claims Act
(R.I. Gen. Laws § 9-1.1-1, *et seq.*)

496. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

497. This is a *qui tam* action brought by Relator on behalf of the State of Rhode Island to recover treble damages and civil penalties under the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1, *et seq.*

498. Rhode Island's False Claims Act, Gen. Laws 1956, § 9-1.1-3, provides for liability for any person who:

(1) Knowingly presents, or causes to be presented a false or fraudulent

claim for payment or approval;

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(3) Conspires to commit a violation of subdivisions 9-1.1-3(1), (2), (3), (4), (5), (6) or (7);

(4) Has possession, custody, or control of property or money used, or to be used, by the state and knowingly delivers, or causes to be delivered, less property than all of that money or property;

(5) Is authorized to make or deliver a document certifying receipt of property used, or to be used, by the state and, intending to defraud the state, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the state, or a member of the guard, who lawfully may not sell or pledge the property; or

(7) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state.

499. Defendants violated the Rhode Island False Claims Act and knowingly caused false claims to be made, used and presented to the State of Rhode Island by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

500. The State of Rhode Island, by and through the Rhode Island Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

501. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and also an express condition of payment of claims

submitted to the State of Rhode Island in connection with Defendants' conduct. Compliance with applicable Rhode Island statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Rhode Island.

502. Had the State of Rhode Island known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

503. As a result of Defendants' violations of the Rhode Island False Claims Act, the State of Rhode Island has been damaged in an amount far in excess of millions of dollars exclusive of interest.

504. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Rhode Island False Claims Act on behalf of himself and the State of Rhode Island.

505. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Rhode Island in the operation of its Medicaid program.

506. WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the STATE OF RHODE ISLAND:

(1) Three times the amount of actual damages which the State of Rhode Island has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $11,463 and not more than $23,331 for each false claim which Defendants caused to be presented to the State of Rhode Island;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to Rhode Island False Claims Act and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

Count 34
Tennessee Medicaid False Claims Act
(Tenn. Code Ann. § 71-5-181, *et seq.*)

507. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

508. This is a *qui tam* action brought by Relator on behalf of the State of Tennessee to recover treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181, *et seq.*

509. Section 71-5-182(a)(1) provides liability for any person who:

(1) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval under the Medicaid program;

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim under the Medicaid program;

(3) Conspires to commit a violation of subdivision (a)(1)(A), (a)(1)((B), or (a)(1)((D); or

(4) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money, or property to the state, or knowingly conceals, or knowingly and improperly, avoids, or decreases an obligation to pay or transmit money or property to the state, relative to the Medicaid program.

510. Defendants violated Tenn. Code Ann. § 71-5-1 82(a)(1) and knowingly caused false claims to be made, used and presented to the State of Tennessee by the conduct alleged herein and by virtue of the fact that none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

511. The State of Tennessee, by and through the Tennessee Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

512. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Tennessee in connection with Defendants' conduct. Compliance with applicable Tennessee statutes was also a condition of payment of claims submitted to the State of Tennessee.

513. Had the State of Tennessee known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

514. As a result of Defendants' violations of Tenn. Code Ann. § 71-5-182(a)(1), the State of Tennessee has been damaged in an amount far in excess of millions of dollars exclusive of interest.

515. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Tenn. Code Ann. § 71-5-183(a)(1) on behalf of himself and the State of Tennessee.

516. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Tennessee in the operation of its Medicaid program.

517. WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the STATE OF TENNESSEE:

(1) Three times the amount of actual damages which the State of Tennessee has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,000 and not more than $25,000 for each false claim which Defendants caused to be presented to the State of Tennessee, except that this upper limit on liability is subject to an automatic adjustment in accordance with the CPIAA;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to Tenn. Code Ann. § 71-5-183(c) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

Count 35
Texas False Claims Act
(Tex. Hum. Res. Code § 36.001, *et seq.*)

518. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

519. This is a *qui tam* action brought by Relator on behalf of the State of Texas to recover double damages and civil penalties under Tex. Hum. Res. Code § 36.001, *et seq.*

520. Tex. Hum. Res. Code § 36.002 provides liability for any person who:

(1) knowingly makes or causes to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized;

(2) knowingly conceals or fails to disclose information that permits a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized;

(3) knowingly applies for and receives a benefit or payment on behalf of another person under the Medicaid program and converts any part of the benefit or payment to a use other than for the benefit of the person on whose behalf it was received;

(4) knowingly makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:

a. the conditions or operation of a facility in order that the facility may qualify for certification or recertification required by the Medicaid program, including certification or recertification as . . . .

b. information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;

(5) except as authorized under the Medicaid program, knowingly pays, charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or product or the continued provision of a service or product if the cost of the service or product is paid for, in whole or in part, under the Medicaid program;

(6) knowingly presents or causes to be presented a claim for payment under the Medicaid program for a product provided or a service rendered by a person who:

a. is not licensed to provide the product or render the service, if a license is required; or

b. is not licensed in the manner claimed;

(7) knowingly makes or causes to be made a claim under the Medicaid program for:

a. a service or product that has not been approved or acquiesced in by a treating physician or health care practitioner;

b. a service or product that is substantially inadequate or inappropriate when compared to generally recognized standards within the particular discipline or within the health care industry; or

c. a product that has been adulterated, debased, mislabeled, or that is otherwise inappropriate;

(8) makes a claim under the Medicaid program and knowingly fails to indicate the type of license and the identification number of the licensed health care provider who actually provided the service;

(9) conspires to commit a violation of Subdivision (1), (2), (3), (4), (5), (6), (7), (8), (10), (11), (12), or (13);

(10) is a managed care organization that contracts with the commission or other state agency to provide or arrange to provide health care benefits or services to individuals eligible under the Medicaid program and knowingly:

a. fails to provide to an individual a health care benefit or service that the organization is required to provide under the contract;

b. fails to provide to the commission or appropriate state agency information required to be provided by law, commission or agency rule, or contractual provision; or

c. engages in a fraudulent activity in connection with the enrollment of an individual eligible under the Medicaid program in the organization's managed care plan or in connection with marketing the organization's services to an individual eligible under the Medicaid program;

(11) knowingly obstructs an investigation by the attorney general of an alleged unlawful act under this section;

(12) knowingly makes, uses, or causes the making or use of a false record or statement material to an obligation to pay or transmit money or property to this state under the Medicaid program, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to this state under the Medicaid program; or

(13) knowingly engages in conduct that constitutes a violation under Section 32.039(b).

521. Defendants violated Tex. Hum. Res. Code § 36.002 and knowingly caused false claims to be made, used and presented to the State of Texas by engaging in the conduct alleged herein and by virtue of the fact that none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

522. The State of Texas, by and through the Texas Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

523. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Texas in connection with Defendants' conduct. Compliance with applicable Texas statutes was also a condition of payment of claims submitted to the State of Texas.

524. Had the State of Texas known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

525. As a result of Defendants' violations of Tex. Hum. Res. Code § 36.002, the State of Texas has been damaged in an amount far in excess of millions of dollars exclusive of interest.

526. Defendants did not, within 30 days after they first obtained information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and

has not otherwise furnished information to the State regarding the claims for reimbursement at issue.

527. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Tex. Hum. Res. Code § 36.101 on behalf of himself and the State of Texas.

528. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Texas in the operation of its Medicaid program.

529. WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the STATE OF TEXAS:

(1) Two times the amount of actual damages which the State of Texas has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $11,463 and not more than $23,331 pursuant to Tex. Hum. Res. Code § 36.052 for each false claim which Defendants caused to be presented to the state of Texas, except that this upper limit on liability is subject to an automatic adjustment in accordance with the CPIAA;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to Tex. Hum. Res. Code § 36.110, and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

[UNDER SEAL],

Plaintiff,

v.

[UNDER SEAL],

Defendants.

Civil Action No.: 20-CV-3207 (MKV)

FIRST AMENDED COMPLAINT

FILED UNDER SEAL
PURSUANT TO
31 U.S.C. § 3730(b)(2)

DEMAND FOR JURY TRIAL